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Journal:	*BMJ Open*
Manuscript ID:	bmjopen-2013-004561
Article Type:	Research
Date Submitted by the Author:	26-Nov-2013
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Primary Subject Heading:	Qualitative research
Secondary Subject Heading:	Patient-centred medicine, Mental health, Haematology (incl blood transfusion), Communication
Keywords:	Thromboembolism < CARDIOLOGY, Anticoagulation < HAEMATOLOGY, Anxiety disorders < PSYCHIATRY, QUALITATIVE RESEARCH, VASCULAR MEDICINE

The long-term psychological consequences of symptomatic pulmonary embolism: a qualitative study.

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Objective

To explore the psychological consequences of experiencing symptomatic pulmonary embolism.

Design

Qualitative interview based study using interpretative phenomenological analysis.

Setting

Outpatients who attended an anticoagulation clinic in a district general hospital.

Participants

Patients attending an anticoagulation clinic following hospital admission for symptomatic pulmonary embolism were approached to participate. A total of nine (4 female, 5 male) out of 11 patients approached, agreed to be interviewed. Participants were aged between 26 and 72 years and had experienced a PE between 9 and 60 months previously (median=26 months, mean=24 months).

Intervention

Audiotaped semi structured qualitative interviews were undertaken to explore participants experiences of having a PE and how it had affected their lives since. Data was transcribed and analysed using interpretative phenomenological analysis to identify emergent themes.

Results

Three major themes with associated sub themes were identified. Participants described having a PE as a life changing experience comprising of initial shock, followed by feeling of loss of self, life changing decisions and behavior modification. Features of post-traumatic stress disorder (PTSD) were described with flashbacks, hypervigilance and intrusive thoughts being most prevalent. Participants identified several areas of support needed for such patients including easier access to support through information giving and emotional support.

Conclusion

The long-term consequences of VTE go beyond the physical alone. Patients describe experiencing symptomatic PE to be a life changing distressing event leading to behaviour modification and in some PTSD. It is likely that earlier psychological intervention may reduce such long-term sequelae.

Strengths of this study

- This is the first time the psychological consequences of a common medical condition have been explored.
- This paper highlights an unmet clinical need
- This paper is of relevance to a breadth of health professionals
- This paper gives patients a voice

Weaknesses of the study

- The patients were recruited from a single site
- Whilst appropriate in number for interpretative phenomenological analysis, the number of participants are small
- The data cannot be generalised among all PE patients but highlights the need to explore the area further.

Venous thromboembolism (VTE), clinically presenting as deep venous thrombosis (DVT) or pulmonary embolism (PE), remains a major cause of morbidity and mortality worldwide, affecting 1 in 1000 patients annually(1). The long-term physical consequences of venous thromboembolism are well documented; post-thrombotic syndrome (PTS) complicates between 25 - 50% DVT cases (2-5) and 0.4 - 4% of patients who experience PE will develop chronic thromboembolic pulmonary hypertension (CTPH)(6-8). Both these complications represent a considerable healthcare burden. Patients with PTS may not only require long-term compression stockings but also endovascular surgery if symptoms prove refractory (9). For patients who develop CTPH, medical therapy is yet to demonstrate any survival advantage leaving pulmonary thromboendarterectomy as the treatment of choice (10, 11). However only half of the patients will qualify for surgery and, of the remainder, 50% are likely to die within a year if their mean pulmonary arterial pressure exceeds 50 mmHg(11, 12).

The long-term sequelae following acute VTE go beyond the physical alone. The development of PTS appears to have a negative impact on quality of life (QoL) in patients experiencing VTE (13, 14). Using the Venous Insufficiency Epidemiologic and Economic Study quality-of-life questionnaire (VEINES-QOL) and its validated subscale of 10 items on venous symptoms (VEINES-Sym), patients with PTS were shown to have significantly worse disease-specific quality-of-life scores than those without PTS ($P = 0.003$), which worsened significantly with increasing severity of PTS (13, 14). Furthermore, the development of PTS is considered major determinant of a patients' health related QoL two years after VTE (14).

Whilst the physical consequences of VTE have been extensively reported, the possible impact of VTE on patients' psychological and emotional well-being has received little attention. Other common and potentially life-threatening conditions such as cancer and myocardial infarction have been researched extensively with clear evidence that such illnesses can result in significant psychological morbidity. To date, no studies have investigated the impact of VTE on everyday life.

The experience of any health related crisis is likely to result in some form of emotional distress presenting in a variety of forms including worry, anxiety, intrusive ideation and dysphoric mood, amongst other negative emotional reactions(15, 16). This appears most pronounced in medical events that pose a significant threat to life and can manifest as anxiety, anger, depression and even symptoms of post-traumatic stress disorder (PTSD) (17-20). Historically PTSD has been associated with experiences of war, rape or attempted murder, where the individual is exposed to an external threat to the physical integrity of themselves or others. However research now suggests PTSD may also arise from internal physical experiences, particularly those associated with a direct or imminent threat to life(21, 22).

Life-threatening and traumatic medical events are those most likely to cause psychological distress and behavioural changes associated with symptoms of PTSD (23). Risk for PTSD is heightened by the perception of uncertainty and/or unpredictability associated with the traumatic medical experience and worsened where the patient believes adverse outcomes to be inevitable or largely uncontrollable (24, 25). Since VTE is a potentially life threatening condition which often occurs in previously well patients, coupled with the uncertainty of recurrence it is possible that such patients are at increased risk of emotional distress, especially those who have experienced major PE(26). We therefore conducted a study to explore the psychological impact of VTE in patients who had experienced a major symptomatic PE.

Methods

This study was undertaken using qualitative methodologies, which have previously been used to evaluate patient experience and clinician attitudes regarding VTE management (27-29).

Ethical approval was obtained through the NHS South Wales Research Ethics Committee. Patients attending a dedicated haematology/ thrombosis clinic, within a district general hospital, were sequentially screened for inclusion into the study and invited by letter to participate. All eligible patients were invited to participate.

Inclusion criteria:

- Aged between 18 and 70 years of age
- Patients who had experienced a symptomatic PE which resulted in admission to hospital
- Able to consent and participate in a 30-minute interview.

Exclusion criteria:

- Presence of cancer
- Known history of previous mental illness or psychological distress prior to PE

Semi-structured interviews were carried out over a twelve-month period by two female researchers (RL and JW) as part of an MSc research project under the supervision of PB and SN. Both researchers were experienced in the filed of clinical psychology and trained in conducting qualitative research. Following initial pilot testing, the interviews were conducted within patients' homes and guided by a prompt list to ensure that the same issues were discussed at each interview. Researchers had no prior relationship with participants or declared clinical interest in VTE management. Data were elicited on the following:

- Their experience of suffering a major PE, and
- How they felt this had affected or influenced their day-to-day lives in terms of
  - Routines and activities
  - Feelings, attitudes and beliefs about themselves

To facilitate this, questions were open-ended with the use of prompts to probe further into issues, which arose as significant or meaningful to the participant. Interviews were digitally recorded and transcribed verbatim. Field notes were also taken. Interviews took approximately thirty minutes each.

Analysis

The analytic framework for this qualitative study was based on Interpretative Phenomenological Analysis (IPA)(30). IPA aims to explore how participants make sense of their experience but is also interpretative, recognising the researcher's conceptions, and experience, as brought to the analysis.

The data was analysed in the following stages:

- The first transcript was read line-by-line and annotated with initial comments.
- Initial comments were grouped into themes.
- Connections between themes were developed until an organised master list and thematic rationale was achieved.
- New themes were tested against the previous transcripts as non-recurring themes were tested against following transcripts. Connections across cases were noted to identify a set of super-ordinate themes for the group.

A coding framework for emergent themes was then developed and applied across the data corpus. Initial coding was undertaken independently by RL and JW and then validated by SN and PB.

Results

Participant characteristics

Of eleven eligible participants invited, nine (5 male and 4 female) agreed to participate in the study. Previous IPA-based studies within the field of health psychology have recommended a minimum of three to six participants to achieve saturation of themes (30). Patient characteristics are summarised in table 1. Patients were aged between 26 and 72 years old (median=44, mean=45). All patients had been hospitalized following a symptomatic PE between 9 and 60 months previously (median=26 months, mean=24 months). The majority of patients presented with progressive dyspnea. Two described sudden onset symptoms and two patients had cardiovascular compromise from the PE. Two major themes were identified with associated subthemes Major themes with associated subthemes identified are summarized in figure one and were: PE as a life changing event, development of post traumatic stress disorder and identification of support needs.

Major theme 1: Life changing event

Patients viewed their experience of a PE as a life-changing event, which had significant impact on their emotions, behaviors and how they viewed themselves and the future. Having gone from being healthy individuals with no major co-morbidities patients reported on-going and significant emotional distress following their diagnosis. The major components of this distress came from the initial shock of the diagnosis and ongoing uncertainty of the future.

Shock/ distress at uncertainty

Patients described uncertainty as a prominent source of emotional distress and discontent, as well as having impacted on how they behave in their day-to-day lives. Uncertainty was most commonly associated with feelings of worry and anxiety in relation to 'not knowing' and concerns about treatment, their future health and life-expectancy and the physical effects of their condition on their day-to-day life. For example, patients often referred to feelings of worry and anxiety in relation to not knowing whether or when they would experience another major PE.

> *"So I think having to live with that, the uncertainty, has caused me to worry a lot because no one can say for definite that A, it will never happen and B if it did it would never get to the level where next time I wouldn't be so lucky. I think that's the hardest part, just not knowing if or when it's ever going to happen again".* 2F
>
> *"But, it was just a bit, a bit of a shock because obviously, I am young, and it doesn't really happen to people, my age, without you know, actual problems with the blood..."* 8F
>
> *"...it got me down first of all, it, bit of a shock, 'cause I wouldn't expect it to be a clot, I thought it was just a nasty bruise..."* 9M

Patients also expressed emotional distress in relation to not knowing the cause of their major PE or why they have experienced a decrease in physical fitness.

> *"I just couldn't understand why it had happened to me. Why me? It was awful not knowing what had caused it."* 2F

In a number of cases, patients described feelings of worry and anxiety and consequent restriction or withdrawal from physical activities due to having become 'hyper-vigilant' to bodily sensations due to uncertainties about not knowing or understanding the meaning or implications behind experiencing such bodily sensations. Patients referred to discerning bodily sensations such as breathlessness or increased heart rate, often experienced with attempts at physical activity as being similar to their original symptoms and thus interpreted to indicate a negative, catastrophic outcome (e.g. recurrence or death from major PE).

> *"… frightened if I'm honest, because…um…I wasn't sure what it was, I thought it was pleurisy so, initially I just thought well, it's pleurisy, it's painful, and it's fine, but once I knew it was blood clots, and the Consultant said, sometimes these damage the outside of the heart, I was scared, in fact, when the Consultant left, um, and I was on my own, I got a bit tearful, it was, I thought, well, this is life threatening."* 7M

> *"I slightly panicked a bit later on when I sort of recovered, because I had felt very dizzy at that point, the nurse explained to me that my heart rate dropped to thirty and that's when I first probably realized you know, the potential outcome could be, very bad."* 6M

Loss of self

Participants reported feelings of losing who they were, in particular with respect to no longer undertaking activities or behaviors that they previously identified as part of their core characteristics. The loss of self was considered more profound owing to the suddenness of the PE event from which they attributed the loss of self to originate. For some, the loss of self appeared to originate from the physical restrictions they found imposed upon them from the PE itself. For others the changes in activities resulted from being anticoagulated, thus needing to avoid activities that had a high risk of trauma and bleeding.

> *"I just find it difficult to comprehend that overnight I went from being fit, doing most things that people are able to do at my age without any problems at all, and in the twinkling of an eye reduced to not even being able to walk even ten yards across a ward to the toilet. I just don't see myself as fit anymore."* 4M
>
> *"Since I've had this he hasn't mentioned taking over the business because he's seen such a change in me that he knows that I'm not capable of doing it. And deep down, that hurts me more than anything".* 3F
>
> *"It hurts me to think that they don't see me as the fun, active mum I used to be, and I think they do resent me for it."* 3F
>
> *"…it's had a bit of a deeper effect on me really, because, I've had to stop all the things I used to do, I was really into rugby, which is obviously quite a contact sport, um… surfing, um, and karate which is full contact as well, and my whole lifestyle was, sort of a, so I've had to stop everything…" 6M*
>
> *"…I was told I can't really drink much and that's all I used to do on a Saturday after rugby and, so socially I'm not as active as I was…"6M*
>
> *"I hate it really…, really upsetting really 'cause I can't do anything I used to do, like doing." 9M*

Change in focus or direction

All participants reported their experience of PE to have affected how they viewed and approached the future. Some adopted a fatalistic or nihilistic approach, suggesting they no longer felt in control of their destiny, which was at the mercy of future thrombotic events.

> *"It doesn't give you a very good outlook does it? I try not to think ten years time, twenty years time you know what I mean?"* 3F

> *"Ninety eight percent of the time I'm very fatalistic about it all now….I've kind of accepted my lot."*5M

Many considered their experience as an opportunity to re-evaluate their lives and take positive steps to optimize their future. Some described a newfound appreciation of what was important to them, whilst others had made changes to their careers or their lifestyles.

> *"But then I guess I'm lucky to still be alive. You know I'm still here….I've just got to accept that as much as it hurts, I want to see my girls grow up…So I've just got to be positive and grateful for what I have got. And thinking like that has helped me to go on with my life."* 3F

> *"I've gone into care work now which is great because I've got the strength to help people and its nice that I can relate to people who've had strokes and such because I think 'I ain't half lucky', you I feel so blessed and lucky that I'm still here to help people you know. So for me its made me have a sort of different outlook on life but sort of more positive."* 3F

> *"But, um, I do consider things to be a bit more, *pause* cherishing, have some cherished moments *laughs* especially straight after…now, I just feel like I'm back to normal…but I'm trying to make the most of, what I've got…which isn't a lot…"* 8F

> *"I've um, looked at what do I need to do to improve my chances of, um, living a healthy lifestyle…so I've been now to see a nutritionist for healthy eating…I don't drink um, more than 2-3 units a day, and I'll have a couple of days off which I wouldn't have done before, and I'm trying to look at my food intake and what I'm eating, to try to lose weight… so I'm just trying to*

> *be more sensible about my eating and drinking habits and being more focused on my exercise.”* 7M

Avoidance behaviours

Participants frequently described a modification in their day-to-day behaviours. They avoided any activity they perceived could precipitate a further PE and those receiving anticoagulation avoided anything that might increase their risk of bleeding complications. Modification of physical activity and exertion was the commonest behavior change in order to minimise exposure to potential physical trauma.

> *“I was quite outgoing and robust…feel like I’ve gone more timid…I don’t get involved in anything…I’m afraid I’ll bang my head…I just really, really refrain from doing much.”*6M

> *“…I’m certainly very careful, I don’t get any cuts that you know, are unnecessarily from silly little things, so you’d be careful around being um, uh…when I was out on the road bike cycling or you know, sometimes I wouldn’t put my helmet on, now I always put my helmet on, so it’s just made me be a bit more careful around what I’m doing incase I you know, bleed or um, or something happens from that.” M7*

Major theme 2: Post Traumatic Stress Disorder

Post traumatic stress disorder (PTSD) is characterized by a group of symptoms including flashbacks, avoidance behaviours, numbing of memories and hyper arousal which continue beyond a month after the traumatic event(31, 32). Almost all participants volunteered symptoms suggestive of PTSD, some describing symptom clusters which suggested a significant degree of functional disability due to the condition.

Flashbacks

Flashbacks to, and memories of, the initial PE experience were common. Ongoing anticoagulation, be it self injecting low molecular weight heparin (LMWH), taking oral anticoagulants or having blood tests acted as profound triggers to flashbacks and reminders of their perceived "near death experience".

> *"All these sorts of things; its brought back to you all the time even when your not consciously thinking about it, its brought back to you all the time."*5M

> *"And then I reverted to injecting myself and then that then carried on but it was just a constant reminder of what had happened, even now, although its become routine, it just makes me think how close I came to almost dying, to how ill I was."*4M

> *"For instance it might be time to my injection and it'll just all come back to me. The worries, will it happen again, will I be so lucky next time?"*2F

Whilst some reported the content of the flashback episode to be short-lived, others experienced a more protracted experience reliving the entire distressing episode.

> *I'll go through the whole thing. Like it will run from start to finish like a movie. Its very hard to switch off once I've started thinking about it, it has to play out if you like"*2F

Numbing of memories

Several participants recalled a blunting of their emotion during the experience with some disassociation with reality.

> *"…some sense which it doesn't seem real…"* 5M
>
> *"…seems like, as if it kind of wasn't real…"* 8F

Others described the use of denial, be it conscious or sub conscious in dealing with the trauma of the experience.

> *"…for a long time I was just, well, in denial I think, "oh no, I'll be alright, I'll be alright…"*6M
>
> *"But when they (thoughts/feelings associated with major PE) come to the surface, well I have puzzles and things which I do to block it out…I don't want to think about it so my puzzles are one way of avoiding thinking about it for me."* 1F

Hyper vigilance

Patients reported increased increased vigilance and awareness of anxiety any symptoms they felt could be associated with a recurrent PE. Such awareness was associated with increased anxiety and catastrophising thought processes.

> *"In the beginning I was very very very weary, very scared. I would only have to get a sort of sign or niggle in my chest and I would start to panic thinking that it was going to happen again or I'd end up in a heap on the floor"*2F

> *"It was always on my mind. It made me more conscious of making sure that if I was on my own somewhere people knew….I taught my daughter nannies house number…just in case something did happen. It just makes me angry to think that no-one can tell me I won't have another one and now I have to live my life by this"*2F

Major theme 3: Support needs

All participants described needing a significant degree of support and it was evident that the support needed was ongoing but differed over time. The nature of support required often required clinical and or specialist knowledge, and appeared to be an unmet need which could only be met by appropriate healthcare professionals.

Information

During the initial stages of diagnosis and treatment, participants required considerable information regarding their condition, their prognosis and long term treatment. Many described their care as focusing on the biomedical with little attention given to support through information giving or psychological care.

> *"None of them actually said anything to make me understand, it was just a case of 'you've had these clots, they've gone to your lungs', none of the rest of what else could have happened before they got to the lungs registered or how serious it was when it got to there."*5F

Where information was not freely available, participants would seek answers on the Internet. This form of information gathering, without access to additional support or proved more distressing than helpful.

> *"Yeah after looking on the internet I did the whole sitting, crying, rocking thing thinking 'oh me god' and then told myself off for looking to be honest because finding out that way with no-one there to kind of go through it with me knocked me for six."* M5

Participants were clear on the degree of information they required: frequently describing the need to understand why this had happened to them and what they should/ should not do from then on to rehabilitate effectively.

> *"It causes me quite a lot of concern doing things…and I'm scared of doing them in case it happens again….I just get so annoyed that's that the thing that will stop me, because I worry that if I get a bit out of breath or feel my*

> *heart going that I'll end up in a heap on the floor basically…but I wouldn't worry as much if I just knew what was causing it, or someone could tell me how much I can push myself"*

> *"It just annoys me because I just can't achieve what I used to achieve and I just haven't got the answers as to why. Why can't I? What's stopping me? What's making that happen to me? If I had the answers I'd be alright with it. I'd get on with it". 3F*

When basic information was provided, including reaslistic outcomes, partcipants were able to make more sense of their lives and symptoms, describing a more positive rehabilitation.

> *"So I asked if he could provide me with some information about what was the likely cause and some information about what I could expect or hope for really in recovering for me which was quite a fortuitous bit of information that I got which encouraged me a bit but it sort of did seem possible that by just keeping on with the blood thinning that these could eventually get re-absorbed and I could get back to sort of normal activity."* 4M

Empathy

Participants considered themselves to have experienced a narrow escape from death and as described before expressed considerable psychological distress after the event. They did not feel that healthcare professionals fully appreciated the seriousness of their experience and thus did not understand the distress associated with symptoms suggestive of VTE recurrence.

> *"But I cant remember thinking that you know, I might have died, that my daughter might not have had her mum, and no one helping to make sure that I understood what was going on, or what was wrong with me, or how this would effect my life. I just remember feeling quite resentful of the medical staff."* 2F

> *"And I did start to panic then and think well you know if I had a pain in the chest again I could be telling someone what I think it is but would they actually take my word for it kind of thing. And I did actually feel that it wasn't really taken too seriously. I mean the fact that it could of killed me and they had a very blasé approach toward it."* 2F

Access to support

Whilst there was a significant requirement for information and support from healthcare professionals, some participants also identified the potential benefits of self-help/ support groups. The opportunity to meet other people who understood their experiences and associated feelings was considered a positive thing and there was a belief that several unmet needs could be provided by fellow PE patients.

> *"I would have loved, and still would like some sort of group thing or support to be available to help me come to terms with what's happened to me…somewhere where somebody could have explained 'yeah its normal to feel like that' etcetera, you know like maybe other people who had been through the same thing. I don't think I would of felt so on my own then…. Just to have this level of conversation with somebody back then would have helped massively. To help me process it all through, because it was very 'off you go' and that was that".* 5M

Discussion

Venous thromboembolism is a common medical condition, which may cause a spectrum of physical symptoms. In its most severe form, major symptomatic pulmonary emboli may lead to cardiovascular compromise and even death. Whilst the long-term complications such as post thrombotic syndrome and pulmonary hypertension are well recognized, little has been known about the psychological impact of symptomatic VTE. In our study of previously healthy adults who experienced a symptomatic pulmonary embolus we have identified that the psychological consequences of experiencing symptomatic VTE are considerable. The development of VTE is considered a life-changing event with some patients feeling a loss of identity and role in life. More concerning appears to be a profound and ongoing collection of symptoms suggestive of the development of PTSD. This is the first time that PTSD has been identified as a consequence of VTE. To some extent these findings shouldn't come as a surprise since features that contribute to the development of PTSD are common in VTE patients; patients of previous good health experience a traumatic life threatening event and the face a future of uncertainty regarding recurrence. However, these findings raise the possibility that as healthcare professionals we are failing to recognise the psychological needs of our patients.

There are several limitations to this study: the number of participants is small and although the numbers are appropriate for such qualitative methodology, a larger study is clearly needed to identify the true prevalence of PTSD using a validated screening tool. There is also a possibility of selection bias since all participants interviewed had required admission to hospital for their symptomatic PE and as such were likely to be those with more severe symptoms and thus a more traumatic experience. Whilst the likelihood of bias is acknowledged, it shouldn't invalidate the findings in the context of those with the most significant VTE episodes. It would be presumptive to assume that all VTE patients experienced PTSD in the same way that one acknowledges that PTSD occurs in some but not all myocardial infarction patients. It does, however, highlight that of those developing VTE, a subgroup may experience significant psychological sequelae and it would make clinical sense to identify those at greatest risk and arrange appropriate support. At present it is not possible to identify whether the development of PTSD is directly related to the VTE experience or whether there are particular pre morbid characteristics that predispose people. It is of interest to note that participants felt they received limited information and would have liked more opportunities to understand their condition from an appropriately trained professional rather than seek information themselves on the internet.

Finally this study highlights several areas of opportunity for healthcare professionals to deliver support to patients post VTE be it through information giving, empathy or identifying psychological distress early on. It is possible early intervention may reduce the development of long-term psychological distress and the ongoing challenges it brings.

SN affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

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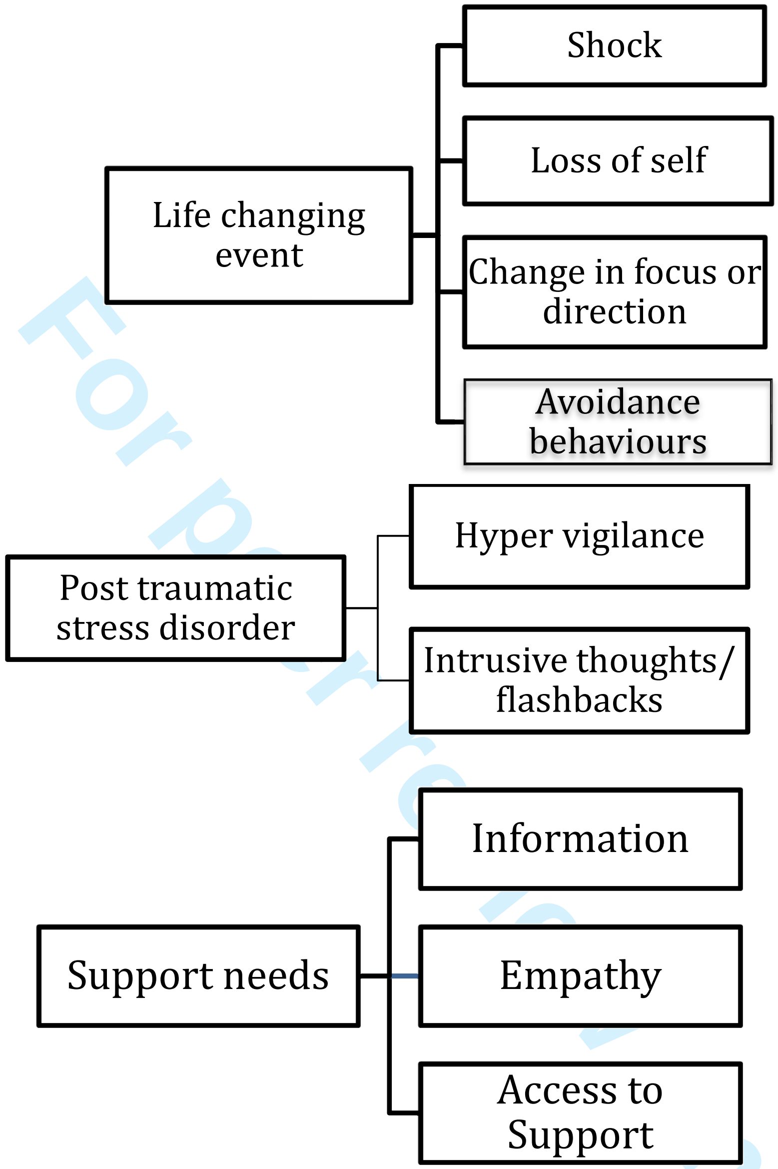
Figure 1: Major themes and associated sub themes



COREC CHECKLIST

All applicable items in the checklist have been addressed within the manuscript. These have been outlined in the comments section of the table below.

No	Item	Guide questions	Comments and page
Domain 1: Research team and reflexivity			
Personal Characteristics			
1.	Interviewer/ facilitator	Which author/s conducted the interview or focus group?	RL and JW
2.	Credentials	What were the researcher's credentials? *E.g. PhD, MD*	MSc students
3.	Occupation	What was their occupation at the time of the study?	MSc students
4.	Gender	Was the researcher male or female?	Female
5.	Experience and training	What experience or training did the researcher have?	Experienced clinical psychologists trained in qualitative research.
Relationship with participants			
6.	Relationship established	Was a relationship established prior to study commencement?	No prior relationship
7.	Participant knowledge of the interviewer	What did the participants know about the researcher? e.*g. personal goals, reasons for doing the research*	No prior knowledge
8.	Interviewer characteristics	What characteristics were reported about the interviewer/facilitator? e.g. *Bias, assumptions, reasons and interests in the research topic*	No stated previous interest in VTE management

Domain 2: study design			
Theoretical framework			
9.	Methodological orientation and Theory	What methodological orientation was stated to underpin the study? *e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis*	Interpretative phenomenological analysis
Participant selection			
10.	Sampling	How were participants selected? *e.g. purposive, convenience, consecutive, snowball*	Sequential screening
11.	Method of approach	How were participants approached? e.*g. face-to-face, telephone, mail, email*	Eleven
12.	Sample size	How many participants were in the study?	Nine
13.	Non-participation	How many people refused to participate or dropped out? Reasons?	Two. No reasons sought
Setting			
14.	Setting of data collection	Where was the data collected? e.*g. home, clinic, workplace*	Clinic
15.	Presence of non-participants	Was anyone else present besides the participants and researchers?	No
16.	Description of sample	What are the important characteristics of the sample? *e.g. demographic data, date*	Given in table 1
Data collection			
17.	Interview	Were questions,	Prompt questions

	guide	prompts, guides provided by the authors? Was it pilot tested?	following pilot testing
18.	Repeat interviews	Were repeat interviews carried out? If yes, how many?	No
19.	Audio/visual recording	Did the research use audio or visual recording to collect the data?	Digital audiorecording
20.	Field notes	Were field notes made during and/or after the interview or focus group?	Field notes were taken
21.	Duration	What was the duration of the interviews or focus group?	Thirty minutes
22.	Data saturation	Was data saturation discussed?	No since we used interpretative phenomenological analysis
23.	Transcripts returned	Were transcripts returned to participants for comment and/or correction?	No
Domain 3: analysis and findingsz			
Data analysis			
24.	Number of data coders	How many data coders coded the data?	Two
25.	Description of the coding tree	Did authors provide a description of the coding tree?	Yes
26.	Derivation of themes	Were themes identified in advance or derived from the data?	Derived from the data
27.	Software	What software, if applicable, was used to manage the data?	Not applicable
28.	Participant checking	Did participants provide feedback on the findings?	No
Reporting			
29.	Quotations presented	Were participant quotations	Yes

		presented to illustrate the themes / findings? Was each quotation identified? e.*g. participant number*	
30.	Data and findings consistent	Was there consistency between the data presented and the findings?	Yes
31.	Clarity of major themes	Were major themes clearly presented in the findings?	Yes
32.	Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	Yes

The long-term psychological consequences of symptomatic pulmonary embolism: a qualitative study.

Journal:	*BMJ Open*
Manuscript ID:	bmjopen-2013-004561.R1
Article Type:	Research
Date Submitted by the Author:	04-Mar-2014
Complete List of Authors:	Noble, Simon; Cardiff University, Palliative Medicine Lewis, Rhian; Swansea University, Clinical Psychology Whithers, Jodie; Swansea University, Clinical Psychology Lewis, Sarah; Aneurin Bevan University Health Board, Haematology Bennett, Paul; Swansea University, Clinical Psychology
Primary Subject Heading:	Qualitative research
Secondary Subject Heading:	Patient-centred medicine, Mental health, Haematology (incl blood transfusion), Communication
Keywords:	Thromboembolism < CARDIOLOGY, Anticoagulation < HAEMATOLOGY, Anxiety disorders < PSYCHIATRY, QUALITATIVE RESEARCH, VASCULAR MEDICINE

The long-term psychological consequences of symptomatic pulmonary embolism: a qualitative study.

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Keywords: Thromboembolism, Anticoagulation, Anxiety disorders, Qualitative research, Vascular medicine

Word count 4625

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Objective

To explore the psychological consequences of experiencing symptomatic pulmonary embolism.

Design

Qualitative interview based study using interpretative phenomenological analysis.

Setting

Outpatients who attended an anticoagulation clinic in a district general hospital.

Participants

Patients attending an anticoagulation clinic following hospital admission for symptomatic pulmonary embolism were approached to participate. A total of nine (4 female, 5 male) out of 11 patients approached, agreed to be interviewed. Participants were aged between 26 and 72 years and had experienced a PE between 9 and 60 months previously (median=26 months, mean=24 months).

Intervention

Audiotaped semi structured qualitative interviews were undertaken to explore participants experiences of having a PE and how it had affected their lives since. Data was transcribed and analysed using interpretative phenomenological analysis to identify emergent themes.

Results

Three major themes with associated sub themes were identified. Participants described having a PE as a life changing experience comprising of initial shock, followed by feeling of loss of self, life changing decisions and behavior modification. Features of post-traumatic stress disorder (PTSD) were described with flashbacks, hypervigilance and intrusive thoughts being most prevalent. Participants identified several areas of support needed for such patients including easier access to support through information giving and emotional support.

Conclusion

The long-term consequences of VTE go beyond the physical alone. Patients describe experiencing symptomatic PE to be a life changing distressing event leading to behaviour modification and in some PTSD. It is likely that earlier psychological intervention may reduce such long-term sequelae.

Strengths of this study

- This is the first time the psychological consequences of symptomatic pulmonary embolism have been explored.
- This paper highlights an unmet clinical need
- This paper is of relevance to a breadth of health professionals
- This paper gives patients a voice

Weaknesses of the study

- The patients were recruited from a single site
- Whilst appropriate in number for interpretative phenomenological analysis, the number of participants are small
- The data cannot be generalised among all PE patients but highlights the need to explore the area further.

Venous thromboembolism (VTE), clinically presenting as deep venous thrombosis (DVT) or pulmonary embolism (PE), remains a major cause of morbidity and mortality worldwide, affecting 1 in 1000 patients annually(1). The long-term physical consequences of venous thromboembolism are well documented; post-thrombotic syndrome (PTS) complicates between 25 - 50% DVT cases (2-5) and 0.4 - 4% of patients who experience PE will develop chronic thromboembolic pulmonary hypertension (CTPH)(6-8). Both these complications represent a considerable healthcare burden. Patients with PTS may not only require long-term compression stockings but also endovascular surgery if symptoms prove refractory (9). For patients who develop CTPH, medical therapy is yet to demonstrate any survival advantage leaving pulmonary thromboendarterectomy as the treatment of choice (10, 11). However only half of the patients will qualify for surgery and, of the remainder, 50% are likely to die within a year if their mean pulmonary arterial pressure exceeds 50 mmHg(11, 12).

The long-term sequelae following acute VTE go beyond the physical alone. The development of PTS appears to have a negative impact on quality of life (QoL) in patients experiencing VTE (13, 14). Using the Venous Insufficiency Epidemiologic and Economic Study quality-of-life questionnaire (VEINES-QOL) and its validated subscale of 10 items on venous symptoms (VEINES-Sym), patients with PTS were shown to have significantly worse disease-specific quality-of-life scores than those without PTS (P =0.003), which worsened significantly with increasing severity of PTS (13, 14). Furthermore, the development of PTS is considered major determinant of a patients' health related QoL two years after VTE (14).

Whilst the physical consequences of VTE have been extensively reported, the possible impact of VTE on patients' psychological and emotional well-being has received less attention. Such work has involved the use of validated QoL tools and has focused on the chronic consequences of deep vein thrombosis and less so on pulmonary emboli(15-17). Other common and potentially life-threatening conditions such as cancer and myocardial infarction have been researched extensively with clear evidence that such illnesses can result in significant psychological morbidity. To date, no qualitative studies have investigated the impact of VTE on everyday life.

The experience of any health related crisis is likely to result in some form of emotional distress presenting in a variety of forms including worry, anxiety, intrusive ideation and dysphoric mood, amongst other negative emotional reactions(18, 19). This appears most pronounced in medical events that pose a significant threat to life and can manifest as anxiety, anger, depression and even symptoms of post-traumatic stress disorder (PTSD) (1, 20-22). Historically PTSD has been associated with experiences of war, rape or attempted murder, where the individual is exposed to an external threat to the physical integrity of themselves or others. However research now suggests PTSD may also arise from internal physical experiences, particularly those associated with a direct or imminent threat to life(23, 24).

Life-threatening and traumatic medical events are those most likely to cause psychological distress and behavioural changes associated with symptoms of PTSD (25). Risk for PTSD is heightened by the perception of uncertainty and/or unpredictability associated with the traumatic medical experience and worsened where the patient believes adverse outcomes to be inevitable or largely uncontrollable (26, 27). Since VTE is a potentially life threatening condition which often occurs in previously well patients, coupled with the uncertainty of recurrence it is possible that such patients are at increased risk of emotional distress, especially those who have experienced major PE(28). We therefore conducted a study to explore the psychological impact of VTE in patients who had experienced a major symptomatic PE.

Methods

This study was undertaken using qualitative methodologies, which have previously been used to evaluate patient experience and clinician attitudes regarding VTE management (29-31).

Ethical approval was obtained through the NHS South Wales Research Ethics Committee. Patients attending a dedicated haematology/ thrombosis clinic, within a district general hospital, were sequentially screened for inclusion into the study and invited by letter to participate. All eligible patients were invited to participate.

Inclusion criteria:

- Aged between 18 and 70 years of age
- Patients who had experienced a symptomatic PE which resulted in admission to hospital
- Able to consent and participate in a 30-minute interview.

Exclusion criteria:

- Presence of cancer
- Known history of previous mental illness or psychological distress prior to PE

Semi-structured interviews were carried out over a twelve-month period by two female researchers (RL and JW) as part of an MSc research project under the supervision of PB and SN. Both researchers were experienced in the field of clinical psychology and trained in conducting qualitative research. Following initial pilot testing, the interviews were conducted within patients' homes and guided by a prompt list to ensure that the same issues were discussed at each interview. Researchers had no prior relationship with participants or declared clinical interest in VTE management. Data were elicited on the following:

- Their experience of suffering a major PE, and
- How they felt this had affected or influenced their day-to-day lives in terms of
  - Routines and activities
  - Feelings, attitudes and beliefs about themselves

To facilitate this, questions were open-ended with the use of prompts to probe further into issues, which arose as significant or meaningful to the participant. Interviews were digitally recorded and transcribed verbatim. Field notes were also taken. Interviews took approximately thirty minutes each.

Analysis

The analytic framework for this qualitative study was based on Interpretative Phenomenological Analysis (IPA)(32). IPA aims to explore how participants make sense of their experience but is also interpretative, recognising the researcher's conceptions, and experience, as brought to the analysis.

The data was analysed in the following stages:

- The first transcript was read line-by-line and annotated with initial comments.
- Initial comments were grouped into themes.
- Connections between themes were developed until an organised master list and thematic rationale was achieved.
- New themes were tested against the previous transcripts as non-recurring themes were tested against following transcripts. Connections across cases were noted to identify a set of super-ordinate themes for the group.

A coding framework for emergent themes was then developed and applied across the data corpus. Initial coding was undertaken independently by RL and JW and then validated by SN and PB.

Results

Participant characteristics

Of eleven eligible participants invited, nine (5 male and 4 female) agreed to participate in the study. Previous IPA-based studies within the field of health psychology have recommended a minimum of three to six participants to achieve saturation of themes (32). Patient characteristics are summarised in table 1. Patients were aged between 26 and 72 years old (median=44, mean=45). All patients had been hospitalized following a symptomatic PE between 9 and 60 months previously (median=26 months, mean=24 months). The majority of patients presented with progressive dyspnea. Two described sudden onset symptoms and two patients had cardiovascular compromise from the PE. Two major themes were identified with associated subthemes (Figure 1). Major themes with associated subthemes identified are summarized in figure one and were: PE as a life changing event, development of post traumatic stress disorder and identification of support needs.

Major theme 1: Life changing event

Patients viewed their experience of a PE as a life-changing event, which had significant impact on their emotions, behaviors and how they viewed themselves and the future. Having gone from being healthy individuals with no major co-morbidities patients reported on-going and significant emotional distress following their diagnosis. The major components of this distress came from the initial shock of the diagnosis and ongoing uncertainty of the future.

Shock/ distress at uncertainty

Patients described uncertainty as a prominent source of emotional distress and discontent, as well as having impacted on how they behave in their day-to-day lives. Uncertainty was most commonly associated with feelings of worry and anxiety in relation to 'not knowing' and concerns about treatment, their future health and life-expectancy and the physical effects of their condition on their day-to-day life. For example, patients often referred to feelings of worry and anxiety in relation to not knowing whether or when they would experience another major PE.

> *"So I think having to live with that, the uncertainty, has caused me to worry a lot because no one can say for definite that A, it will never happen and B if it did it would never get to the level where next time I wouldn't be so lucky. I think that's the hardest part, just not knowing if or when it's ever going to happen again".* 2F

> *"But, it was just a bit, a bit of a shock because obviously, I am young, and it doesn't really happen to people, my age, without you know, actual problems with the blood..."* 8F

> *"...it got me down first of all, it, bit of a shock, 'cause I wouldn't expect it to be a clot, I thought it was just a nasty bruise..."* 9M

Patients also expressed emotional distress in relation to not knowing the cause of their major PE or why they have experienced a decrease in physical fitness.

> *"I just couldn't understand why it had happened to me. Why me? It was awful not knowing what had caused it."* 2F

In a number of cases, patients described feelings of worry and anxiety and consequent restriction or withdrawal from physical activities due to having become 'hyper-vigilant' to bodily sensations due to uncertainties about not knowing or understanding the meaning or implications behind experiencing such bodily sensations. Patients referred to discerning bodily sensations such as breathlessness or increased heart rate, often experienced with attempts at physical activity as being similar to their original symptoms and thus interpreted to indicate a negative, catastrophic outcome (e.g. recurrence or death from major PE).

> *"… frightened if I'm honest, because…um…I wasn't sure what it was, I thought it was pleurisy so, initially I just thought well, it's pleurisy, it's painful, and it's fine, but once I knew it was blood clots, and the Consultant said, sometimes these damage the outside of the heart, I was scared, in fact, when the Consultant left, um, and I was on my own, I got a bit tearful, it was, I thought, well, this is life threatening."* 7M

> *"I slightly panicked a bit later on when I sort of recovered, because I had felt very dizzy at that point, the nurse explained to me that my heart rate dropped to thirty and that's when I first probably realized you know, the potential outcome could be, very bad."* 6M

Loss of self

Participants reported feelings of losing who they were, in particular with respect to no longer undertaking activities or behaviors that they previously identified as part of their core characteristics. The loss of self was considered more profound owing to the suddenness of the PE event from which they attributed the loss of self to originate. For some, the loss of self appeared to originate from the physical restrictions they found imposed upon them from the PE itself. For others the changes in activities resulted from being anticoagulated, thus needing to avoid activities that had a high risk of trauma and bleeding.

> *"I just find it difficult to comprehend that overnight I went from being fit, doing most things that people are able to do at my age without any problems at all, and in the twinkling of an eye reduced to not even being able to walk even ten yards across a ward to the toilet. I just don't see myself as fit anymore."* 4M

> *"Since I've had this he hasn't mentioned taking over the business because he's seen such a change in me that he knows that I'm not capable of doing it. And deep down, that hurts me more than anything".* 3F

> *"It hurts me to think that they don't see me as the fun, active mum I used to be, and I think they do resent me for it."* 3F

> *"…it's had a bit of a deeper effect on me really, because, I've had to stop all the things I used to do, I was really into rugby, which is obviously quite a contact sport, um… surfing, um, and karate which is full contact as well, and my whole lifestyle was, sort of a, so I've had to stop everything…"* 6M

> *"…I was told I can't really drink much and that's all I used to do on a Saturday after rugby and, so socially I'm not as active as I was…"6M*
> *"I hate it really…, really upsetting really 'cause I can't do anything I used to do, like doing." 9M*

Change in focus or direction

All participants reported their experience of PE to have affected how they viewed and approached the future. Some adopted a fatalistic or nihilistic approach, suggesting they no longer felt in control of their destiny, which was at the mercy of future thrombotic events.

> *"It doesn't give you a very good outlook does it? I try not to think ten years time, twenty years time you know what I mean?"* 3F

> *"Ninety eight percent of the time I'm very fatalistic about it all now….I've kind of accepted my lot."*5M

Many considered their experience as an opportunity to re-evaluate their lives and take positive steps to optimize their future. Some described a newfound appreciation of what was important to them, whilst others had made changes to their careers or their lifestyles.

> *"But then I guess I'm lucky to still be alive. You know I'm still here….I've just got to accept that as much as it hurts, I want to see my girls grow up…So I've just got to be positive and grateful for what I have got. And thinking like that has helped me to go on with my life."* 3F

> *"I've gone into care work now which is great because I've got the strength to help people and its nice that I can relate to people who've had strokes and such because I think 'I ain't half lucky', you I feel so blessed and lucky that I'm still here to help people you know. So for me its made me have a sort of different outlook on life but sort of more positive."* 3F

> *"But, um, I do consider things to be a bit more, *pause* cherishing, have some cherished moments *laughs* especially straight after…now, I just feel like I'm back to normal…but I'm trying to make the most of, what I've got…which isn't a lot…"* 8F

> *"I've um, looked at what do I need to do to improve my chances of, um, living a healthy lifestyle…so I've been now to see a nutritionist for healthy eating…I don't drink um, more than 2-3 units a day, and I'll have a couple of days off which I wouldn't have done before, and I'm trying to look at my food intake and what I'm eating, to try to lose weight… so I'm just trying to be more sensible about my eating and drinking habits and being more focused on my exercise."* 7M

Avoidance behaviours

Participants frequently described a modification in their day-to-day behaviours. They avoided any activity they perceived could precipitate a further PE and those receiving anticoagulation avoided anything that might increase their risk of bleeding complications. Modification of physical activity and exertion was the commonest behavior change in order to minimise exposure to potential physical trauma.

> *"I was quite outgoing and robust…feel like I've gone more timid…I don't get involved in anything…I'm afraid I'll bang my head…I just really, really refrain from doing much."*6M

> *"…I'm certainly very careful, I don't get any cuts that you know, are unnecessarily from silly little things, so you'd be careful around being um, uh…when I was out on the road bike cycling or you know, sometimes I wouldn't put my helmet on, now I always put my helmet on, so it's just made me be a bit more careful around what I'm doing incase I you know, bleed or um, or something happens from that." M7*

Major theme 2: Post Traumatic Stress Disorder

Post traumatic stress disorder (PTSD) is characterized by a group of symptoms including flashbacks, avoidance behaviours, numbing of memories and hyper arousal which continue beyond a month after the traumatic event(33, 34). Almost all participants volunteered symptoms suggestive of PTSD, some describing symptom clusters which suggested a significant degree of functional disability due to the condition.

Flashbacks

Flashbacks to, and memories of, the initial PE experience were common. Ongoing anticoagulation, be it self injecting low molecular weight heparin (LMWH), taking oral anticoagulants or having blood tests acted as profound triggers to flashbacks and reminders of their perceived "near death experience".

> *"All these sorts of things; its brought back to you all the time even when your not consciously thinking about it, its brought back to you all the time."*5M

> *"And then I reverted to injecting myself and then that then carried on but it was just a constant reminder of what had happened, even now, although its become routine, it just makes me think how close I came to almost dying, to how ill I was."*4M

> *"For instance it might be time to my injection and it'll just all come back to me. The worries, will it happen again, will I be so lucky next time?"*2F

Whilst some reported the content of the flashback episode to be short-lived, others experienced a more protracted experience reliving the entire distressing episode.

> *I'll go through the whole thing. Like it will run from start to finish like a movie. Its very hard to switch off once I've started thinking about it, it has to play out if you like"*2F

Numbing of memories

Several participants recalled a blunting of their emotion during the experience with some disassociation with reality.

> *"…some sense which it doesn't seem real…"* 5M
> *"…seems like, as if it kind of wasn't real…"* 8F

Others described the use of denial, be it conscious or sub conscious in dealing with the trauma of the experience.

> *"…for a long time I was just, well, in denial I think, "oh no, I'll be alright, I'll be alright…"*6M
> *"But when they (thoughts/feelings associated with major PE) come to the surface, well I have puzzles and things which I do to block it out…I don't want to think about it so my puzzles are one way of avoiding thinking about it for me."* 1F

Hyper vigilance

Patients reported increased increased vigilance and awareness of anxiety any symptoms they felt could be associated with a recurrent PE. Such awareness was associated with increased anxiety and catastrophising thought processes.

> *"In the beginning I was very very very weary, very scared. I would only have to get a sort of sign or niggle in my chest and I would start to panic thinking that it was going to happen again or I'd end up in a heap on the floor"*2F

> *"It was always on my mind. It made me more conscious of making sure that if I was on my own somewhere people knew….I taught my daughter nannies house number…just in case something did happen. It just makes me angry to think that no-one can tell me I won't have another one and now I have to live my life by this"*2F

Major theme 3: Support needs

All participants described needing a significant degree of support and it was evident that the support needed was ongoing but differed over time. The nature of support required often required clinical and or specialist knowledge, and appeared to be an unmet need which could only be met by appropriate healthcare professionals.

Information

During the initial stages of diagnosis and treatment, participants required considerable information regarding their condition, their prognosis and long term treatment. Many described their care as focusing on the biomedical with little attention given to support through information giving or psychological care.

> *"None of them actually said anything to make me understand, it was just a case of 'you've had these clots, they've gone to your lungs', none of the rest of what else could have happened before they got to the lungs registered or how serious it was when it got to there."*5F

Where information was not freely available, participants would seek answers on the Internet. This could result in accessing upsetting information, which without access to additional support or proved more distressing than helpful.

> *"Yeah after looking on the internet I did the whole sitting, crying, rocking thing thinking 'oh me god' and then told myself off for looking to be honest because finding out that way with no-one there to kind of go through it with me knocked me for six."* M5

Participants were clear on the degree of information they required: frequently describing the need to understand why this had happened to them and what they should/ should not do from then on to rehabilitate effectively.

> *"It causes me quite a lot of concern doing things…and I'm scared of doing them in case it happens again….I just get so annoyed that's that the thing that will stop me, because I worry that if I get a bit out of breath or feel my heart going that I'll end up in a heap on the floor basically…but I wouldn't worry as much if I just knew what was causing it, or someone could tell me how much I can push myself"*

> *"It just annoys me because I just can't achieve what I used to achieve and I just haven't got the answers as to why. Why can't I? What's stopping me? What's making that happen to me? If I had the answers I'd be alright with it. I'd get on with it". 3F*

When basic information was provided, including realistic outcomes, partcipants were able to make more sense of their lives and symptoms, describing a more positive rehabilitation.

> *"So I asked if he could provide me with some information about what was the likely cause and some information about what I could expect or hope for really in recovering for me which was quite a fortuitous bit of information that I got which encouraged me a bit but it sort of did seem possible that by just keeping on with the blood thinning that these could eventually get re-absorbed and I could get back to sort of normal activity."* 4M

Empathy

Participants considered themselves to have experienced a narrow escape from death and as described before expressed considerable psychological distress after the event. They did not feel that healthcare professionals fully appreciated the seriousness of their experience and thus did not understand the distress associated with symptoms suggestive of VTE recurrence.

> *"But I cant remember thinking that you know, I might have died, that my daughter might not have had her mum, and no one helping to make sure*

> *that I understood what was going on, or what was wrong with me, or how this would effect my life. I just remember feeling quite resentful of the medical staff."* 2F
>
> *"And I did start to panic then and think well you know if I had a pain in the chest again I could be telling someone what I think it is but would they actually take my word for it kind of thing. And I did actually feel that it wasn't really taken too seriously. I mean the fact that it could of killed me and they had a very blasé approach toward it."* 2F

Access to support

Whilst there was a significant requirement for information and support from healthcare professionals, some participants also identified the potential benefits of self-help/ support groups. The opportunity to meet other people who understood their experiences and associated feelings was considered a positive thing and there was a belief that several unmet needs could be provided by fellow PE patients.

> *"I would have loved, and still would like some sort of group thing or support to be available to help me come to terms with what's happened to me…somewhere where somebody could have explained 'yeah its normal to feel like that' etcetera, you know like maybe other people who had been through the same thing. I don't think I would of felt so on my own then…. Just to have this level of conversation with somebody back then would have helped massively. To help me process it all through, because it was very 'off you go' and that was that".* 5M

Discussion

Venous thromboembolism is a common medical condition, which may cause a spectrum of physical symptoms. In its most severe form, major symptomatic pulmonary emboli may lead to cardiovascular compromise and even death. Whilst the long-term complications such as post thrombotic syndrome and pulmonary hypertension are well recognized, little has been known about the psychological impact of symptomatic VTE. In our study of previously healthy adults who experienced a symptomatic pulmonary embolus we have identified that the psychological consequences of experiencing symptomatic VTE are considerable. The development of VTE is considered a life-changing event with some patients feeling a loss of identity and role in life. More concerning appears to be a profound and ongoing collection of symptoms suggestive of the development of PTSD. This is the first time that PTSD has been identified as a consequence of VTE. To some extent these findings shouldn't come as a surprise since features that contribute to the development of PTSD are common in VTE patients; patients of previous good health experience a traumatic life threatening event and the face a future of uncertainty regarding recurrence. However, these findings raise the possibility that as healthcare professionals we are failing to recognise the psychological needs of our patients.

There are several limitations to this study: the number of participants is small and although the numbers are appropriate for such qualitative methodology, a larger study is clearly needed to identify the true prevalence of PTSD using a validated screening tool. In particular it is not possible to identify whether PTSD may be more prevalent is certain sub groups of patients with PE. Within the group sampled the majority were younger than 45 years old and it is possible that the greater degree of psychological distress is seen in younger patients with less illness experience. Likewise PTSD may be more prevalent in those without obvious precipitating cause of VTE since they will live with ongoing uncertainty regarding recurrence. The long-term treatment plan may also play a role and it would be interesting to see whether PTSD is more likely to develop in those with ongoing reminders of their illness such as long term anticoagulation.

There is a possibility of selection bias since all participants interviewed had required admission to hospital for their symptomatic PE and as such were likely to be those with more severe symptoms and thus a more traumatic experience. Whilst the likelihood of bias is acknowledged, it shouldn't invalidate the findings in the context of those with the most significant VTE episodes. It would be presumptive to assume that all VTE patients experienced PTSD in the same way that one acknowledges that PTSD occurs in some but not all myocardial infarction patients. It does, however, highlight that of those developing VTE, a subgroup may experience significant psychological sequelae and it would make clinical sense to identify those at greatest risk and arrange appropriate support. At present it is not possible to identify whether the development of PTSD is directly related to the VTE experience or whether there are particular pre morbid characteristics that predispose people. It is of interest to note that participants felt they received limited information and would have liked more opportunities to understand their condition from an appropriately trained professional rather than seek information themselves on the internet.

Finally this study highlights several areas of opportunity for healthcare professionals to deliver support to patients post VTE be it through information giving, empathy or identifying psychological distress early on. It is possible early intervention may reduce the development of long-term psychological distress and the ongoing challenges it brings.

SN affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

Contributorship Statement: SN, PB and SL conceived the study. RL and JW undertook interviews. JW,RL, PB and SN undertook analysis of data. All authors contributed to the final manuscript.

Competing Interests: None

Data Sharing Statement: No additional data available.

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Participant/sex	Age in years	Time since PE in months	Addition clinical information
1F	72	12	Sudden collapse with cardiovascular compromise
2F	32	60	Sudden dyspnoea during pregnancy
3F	44	60	Progressive dyspnoea
4M	68	24	Progressive dyspnoea
5M	29	24	Progressive dyspnoea
6M	50	18	Progressive dyspnoea. On life long warfarin.
7M	55	12	Progressive dyspnoea. Initially resistant to warfarin. Receiving LMWH.
8F	26	9	Progressive dyspnoea
9M	28	12	Progressive dyspnoea with cardiovascular compromise.

Table 1 Characteristics of participants (LMWH = low molecular weight heparin)

The long-term psychological consequences of symptomatic pulmonary embolism: a qualitative study.

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Keywords: Thromboembolism, Anticoagulation, Anxiety disorders, Qualitative research, Vascular medicine
Word count 4625

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Objective
To explore the psychological consequences of experiencing symptomatic pulmonary embolism.

Design
Qualitative interview based study using interpretative phenomenological analysis.

Setting
Outpatients who attended an anticoagulation clinic in a district general hospital.

Participants
Patients attending an anticoagulation clinic following hospital admission for symptomatic pulmonary embolism were approached to participate. A total of nine (4 female, 5 male) out of 11 patients approached, agreed to be interviewed. Participants were aged between 26 and 72 years and had experienced a PE between 9 and 60 months previously (median=26 months, mean=24 months).

Intervention
Audiotaped semi structured qualitative interviews were undertaken to explore participants experiences of having a PE and how it had affected their lives since. Data was transcribed and analysed using interpretative phenomenological analysis to identify emergent themes.

Results
Three major themes with associated sub themes were identified. Participants described having a PE as a life changing experience comprising of initial shock, followed by feeling of loss of self, life changing decisions and behavior modification. Features of post-traumatic stress disorder (PTSD) were described with flashbacks, hypervigilance and intrusive thoughts being most prevalent. Participants identified several areas of support needed for such patients including easier access to support through information giving and emotional support.

Conclusion
The long-term consequences of VTE go beyond the physical alone. Patients describe experiencing symptomatic PE to be a life changing distressing event leading to behaviour modification and in some PTSD. It is likely that earlier psychological intervention may reduce such long-term sequelae.

Strengths of this study

- This is the first time the psychological consequences of symptomatic pulmonary embolism~~a common medical condition~~ have been explored.
- This paper highlights an unmet clinical need
- This paper is of relevance to a breadth of health professionals
- This paper gives patients a voice

Weaknesses of the study

- The patients were recruited from a single site
- Whilst appropriate in number for interpretative phenomenological analysis, the number of participants are small
- The data cannot be generalised among all PE patients but highlights the need to explore the area further.

Venous thromboembolism (VTE), clinically presenting as deep venous thrombosis (DVT) or pulmonary embolism (PE), remains a major cause of morbidity and mortality worldwide, affecting 1 in 1000 patients annually(1). The long-term physical consequences of venous thromboembolism are well documented; post-thrombotic syndrome (PTS) complicates between 25 - 50% DVT cases (2-5) and 0.4 - 4% of patients who experience PE will develop chronic thromboembolic pulmonary hypertension (CTPH)(6-8). Both these complications represent a considerable healthcare burden. Patients with PTS may not only require long-term compression stockings but also endovascular surgery if symptoms prove refractory (9). For patients who develop CTPH, medical therapy is yet to demonstrate any survival advantage leaving pulmonary thromboendarterectomy as the treatment of choice (10, 11). However only half of the patients will qualify for surgery and, of the remainder, 50% are likely to die within a year if their mean pulmonary arterial pressure exceeds 50 mmHg(11, 12).

The long-term sequelae following acute VTE go beyond the physical alone. The development of PTS appears to have a negative impact on quality of life (QoL) in patients experiencing VTE (13, 14). Using the Venous Insufficiency Epidemiologic and Economic Study quality-of-life questionnaire (VEINES-QOL) and its validated subscale of 10 items on venous symptoms (VEINES-Sym), patients with PTS were shown to have significantly worse disease-specific quality-of-life scores than those without PTS (P =0.003), which worsened significantly with increasing severity of PTS (13, 14). Furthermore, the development of PTS is considered major determinant of a patients' health related QoL two years after VTE (14).

Whilst the physical consequences of VTE have been extensively reported, the possible impact of VTE on patients' psychological and emotional well-being has received less~~ittle~~ attention. Such work has involved the use of validated QoL tools and has focused on the chronic consequences of deep vein thrombosis and less so on pulmonary emboli(15-17). Other common and potentially life-threatening conditions such as cancer and myocardial infarction have been researched extensively with clear evidence that such illnesses can result in significant psychological morbidity. To date, no qualitative studies have investigated the impact of VTE on everyday life.

The experience of any health related crisis is likely to result in some form of emotional distress presenting in a variety of forms including worry, anxiety, intrusive ideation and dysphoric mood, amongst other negative emotional reactions(18, 19). This appears most pronounced in medical events that pose a significant threat to life and can manifest as anxiety, anger, depression and even symptoms of post-traumatic stress disorder (PTSD) (1, 20-22). Historically PTSD has been associated with experiences of war, rape or attempted murder, where the individual is exposed to an external threat to the physical integrity of themselves or others. However research now suggests PTSD may also arise from internal physical experiences, particularly those associated with a direct or imminent threat to life(23, 24).

Life-threatening and traumatic medical events are those most likely to cause psychological distress and behavioural changes associated with symptoms of PTSD (25). Risk for PTSD is heightened by the perception of uncertainty and/or unpredictability associated with the traumatic medical experience and worsened where the patient believes adverse outcomes to be inevitable or largely uncontrollable (26, 27). Since VTE is a potentially life threatening condition which often occurs in previously well patients, coupled with the uncertainty of recurrence it is possible that such patients are at increased risk of emotional distress, especially those who have experienced major PE(28). We therefore conducted a study to explore the psychological impact of VTE in patients who had experienced a major symptomatic PE.

Methods

This study was undertaken using qualitative methodologies, which have previously been used to evaluate patient experience and clinician attitudes regarding VTE management (29-31).

Ethical approval was obtained through the NHS South Wales Research Ethics Committee. Patients attending a dedicated haematology/ thrombosis clinic, within a district general hospital, were sequentially screened for inclusion into the study and invited by letter to participate. All eligible patients were invited to participate.

Inclusion criteria:

- Aged between 18 and 70 years of age
- Patients who had experienced a symptomatic PE which resulted in admission to hospital
- Able to consent and participate in a 30-minute interview.

Exclusion criteria:
- Presence of cancer
- Known history of previous mental illness or psychological distress prior to PE

Semi-structured interviews were carried out over a twelve-month period by two female researchers (RL and JW) as part of an MSc research project under the supervision of PB and SN. Both researchers were experienced in the fi~~l~~eld of clinical psychology and trained in conducting qualitative research. Following initial pilot testing, the interviews were conducted within patients' homes and guided by a prompt list to ensure that the same issues were discussed at each interview. Researchers had no prior relationship with participants or declared clinical interest in VTE management. Data were elicited on the following:

- Their experience of suffering a major PE, and
- How they felt this had affected or influenced their day-to-day lives in terms of
    - Routines and activities
    - Feelings, attitudes and beliefs about themselves

To facilitate this, questions were open-ended with the use of prompts to probe further into issues, which arose as significant or meaningful to the participant. Interviews were digitally recorded and transcribed verbatim. Field notes were also taken. Interviews took approximately thirty minutes each.

Analysis

The analytic framework for this qualitative study was based on Interpretative Phenomenological Analysis (IPA)(32). IPA aims to explore how participants make sense of their experience but is also interpretative, recognising the researcher's conceptions, and experience, as brought to the analysis.

The data was analysed in the following stages:

- The first transcript was read line-by-line and annotated with initial comments.
- Initial comments were grouped into themes.
- Connections between themes were developed until an organised master list and thematic rationale was achieved.
- New themes were tested against the previous transcripts as non-recurring themes were tested against following transcripts. Connections across cases were noted to identify a set of super-ordinate themes for the group.

A coding framework for emergent themes was then developed and applied across the data corpus. Initial coding was undertaken independently by RL and JW and then validated by SN and PB.

Results

Participant characteristics

Of eleven eligible participants invited, nine (5 male and 4 female) agreed to participate in the study. Previous IPA-based studies within the field of health psychology have recommended a minimum of three to six participants to achieve saturation of themes (32). Patient characteristics are summarised in table 1. Patients were aged between 26 and 72 years old (median=44, mean=45). All patients had been hospitalized following a symptomatic PE between 9 and 60 months previously (median=26 months, mean=24 months). The majority of patients presented with progressive dyspnea. Two described sudden onset symptoms and two patients had cardiovascular compromise from the PE. Two major themes were identified with associated subthemes (Figure 1). Major themes with associated subthemes identified are summarized in figure one and were: PE as a life changing event, development of post traumatic stress disorder and identification of support needs.

Major theme 1: Life changing event

Patients viewed their experience of a PE as a life-changing event, which had significant impact on their emotions, behaviors and how they viewed themselves and the future. Having gone from being healthy individuals with no major co-morbidities patients reported on-going and significant emotional distress following their diagnosis. The major components of this distress came from the initial shock of the diagnosis and ongoing uncertainty of the future.

Shock/ distress at uncertainty

Patients described uncertainty as a prominent source of emotional distress and discontent, as well as having impacted on how they behave in their day-to-day lives. Uncertainty was most commonly associated with feelings of worry and anxiety in relation to 'not knowing' and concerns about treatment, their future health and life-expectancy and the physical effects of their condition on their day-to-day life. For example, patients often referred to feelings of worry and anxiety in relation to not knowing whether or when they would experience another major PE.

> *"So I think having to live with that, the uncertainty, has caused me to worry a lot because no one can say for definite that A, it will never happen and B if it did it would never get to the level where next time I wouldn't be so lucky. I think that's the hardest part, just not knowing if or when it's ever going to happen again".* 2F

> *"But, it was just a bit, a bit of a shock because obviously, I am young, and it doesn't really happen to people, my age, without you know, actual problems with the blood..."* 8F

> *"...it got me down first of all, it, bit of a shock, 'cause I wouldn't expect it to be a clot, I thought it was just a nasty bruise..."* 9M

Patients also expressed emotional distress in relation to not knowing the cause of their major PE or why they have experienced a decrease in physical fitness.

> *"I just couldn't understand why it had happened to me. Why me? It was awful not knowing what had caused it."* 2F

In a number of cases, patients described feelings of worry and anxiety and consequent restriction or withdrawal from physical activities due to having become 'hyper-vigilant' to bodily sensations due to uncertainties about not knowing or understanding the meaning or implications behind experiencing such bodily sensations. Patients referred to discerning bodily sensations such as breathlessness or increased heart rate, often experienced with attempts at physical activity as being similar to their original symptoms and thus interpreted to indicate a negative, catastrophic outcome (e.g. recurrence or death from major PE).

> *"… frightened if I'm honest, because…um…I wasn't sure what it was, I thought it was pleurisy so, initially I just thought well, it's pleurisy, it's painful, and it's fine, but once I knew it was blood clots, and the Consultant said, sometimes these damage the outside of the heart, I was scared, in fact, when the Consultant left, um, and I was on my own, I got a bit tearful, it was, I thought, well, this is life threatening."* 7M

> *"I slightly panicked a bit later on when I sort of recovered, because I had felt very dizzy at that point, the nurse explained to me that my heart rate dropped to thirty and that's when I first probably realized you know, the potential outcome could be, very bad."* 6M

Loss of self

Participants reported feelings of losing who they were, in particular with respect to no longer undertaking activities or behaviors that they previously identified as part of their core characteristics. The loss of self was considered more profound owing to the suddenness of the PE event from which they attributed the loss of self to originate. For some, the loss of self appeared to originate from the physical restrictions they found imposed upon them from the PE itself. For others the changes in activities resulted from being anticoagulated, thus needing to avoid activities that had a high risk of trauma and bleeding.

> *"I just find it difficult to comprehend that overnight I went from being fit, doing most things that people are able to do at my age without any problems at all, and in the twinkling of an eye reduced to not even being able to walk even ten yards across a ward to the toilet. I just don't see myself as fit anymore."* 4M

> *"Since I've had this he hasn't mentioned taking over the business because he's seen such a change in me that he knows that I'm not capable of doing it. And deep down, that hurts me more than anything".* 3F

> *"It hurts me to think that they don't see me as the fun, active mum I used to be, and I think they do resent me for it."* 3F

> *"…it's had a bit of a deeper effect on me really, because, I've had to stop all the things I used to do, I was really into rugby, which is obviously quite a contact sport, um… surfing, um, and karate which is full contact as well, and my whole lifestyle was, sort of a, so I've had to stop everything…"* 6M

> *"…I was told I can't really drink much and that's all I used to do on a Saturday after rugby and, so socially I'm not as active as I was…"*6M
> *"I hate it really…, really upsetting really 'cause I can't do anything I used to do, like doing."* 9M

Change in focus or direction

All participants reported their experience of PE to have affected how they viewed and approached the future. Some adopted a fatalistic or nihilistic approach, suggesting they no longer felt in control of their destiny, which was at the mercy of future thrombotic events.

> *"It doesn't give you a very good outlook does it? I try not to think ten years time, twenty years time you know what I mean?"* 3F

> *"Ninety eight percent of the time I'm very fatalistic about it all now….I've kind of accepted my lot."*5M

Many considered their experience as an opportunity to re-evaluate their lives and take positive steps to optimize their future. Some described a newfound appreciation of what was important to them, whilst others had made changes to their careers or their lifestyles.

> *"But then I guess I'm lucky to still be alive. You know I'm still here….I've just got to accept that as much as it hurts, I want to see my girls grow up…So I've just got to be positive and grateful for what I have got. And thinking like that has helped me to go on with my life."* 3F

> *"I've gone into care work now which is great because I've got the strength to help people and its nice that I can relate to people who've had strokes and such because I think 'I ain't half lucky', you I feel so blessed and lucky that I'm still here to help people you know. So for me its made me have a sort of different outlook on life but sort of more positive."* 3F

> *"But, um, I do consider things to be a bit more, *pause* cherishing, have some cherished moments *laughs* especially straight after…now, I just feel like I'm back to normal…but I'm trying to make the most of, what I've got…which isn't a lot…"* 8F

> *"I've um, looked at what do I need to do to improve my chances of, um, living a healthy lifestyle…so I've been now to see a nutritionist for healthy eating…I don't drink um, more than 2-3 units a day, and I'll have a couple of days off which I wouldn't have done before, and I'm trying to look at my food intake and what I'm eating, to try to lose weight… so I'm just trying to be more sensible about my eating and drinking habits and being more focused on my exercise."* 7M

Avoidance behaviours

Participants frequently described a modification in their day-to-day behaviours. They avoided any activity they perceived could precipitate a further PE and those receiving anticoagulation avoided anything that might increase their risk of bleeding complications. Modification of physical activity and exertion was the commonest behavior change in order to minimise exposure to potential physical trauma.

> *"I was quite outgoing and robust…feel like I've gone more timid…I don't get involved in anything…I'm afraid I'll bang my head…I just really, really refrain from doing much."*6M

> *"…I'm certainly very careful, I don't get any cuts that you know, are unnecessarily from silly little things, so you'd be careful around being um, uh…when I was out on the road bike cycling or you know, sometimes I wouldn't put my helmet on, now I always put my helmet on, so it's just made me be a bit more careful around what I'm doing incase I you know, bleed or um, or something happens from that." M7*

Major theme 2: Post Traumatic Stress Disorder

Post traumatic stress disorder (PTSD) is characterized by a group of symptoms including flashbacks, avoidance behaviours, numbing of memories and hyper arousal which continue beyond a month after the traumatic event(33, 34). Almost all participants volunteered symptoms suggestive of PTSD, some describing symptom clusters which suggested a significant degree of functional disability due to the condition.

Flashbacks

Flashbacks to, and memories of, the initial PE experience were common. Ongoing anticoagulation, be it self injecting low molecular weight heparin (LMWH), taking oral anticoagulants or having blood tests acted as profound triggers to flashbacks and reminders of their perceived "near death experience".

> *"All these sorts of things; its brought back to you all the time even when your not consciously thinking about it, its brought back to you all the time."*5M

> *"And then I reverted to injecting myself and then that then carried on but it was just a constant reminder of what had happened, even now, although its become routine, it just makes me think how close I came to almost dying, to how ill I was."*4M

> *"For instance it might be time to my injection and it'll just all come back to me. The worries, will it happen again, will I be so lucky next time?"*2F

Whilst some reported the content of the flashback episode to be short-lived, others experienced a more protracted experience reliving the entire distressing episode.

> *I'll go through the whole thing. Like it will run from start to finish like a movie. Its very hard to switch off once I've started thinking about it, it has to play out if you like"*2F

Numbing of memories

Several participants recalled a blunting of their emotion during the experience with some disassociation with reality.

> *"…some sense which it doesn't seem real…"* 5M
> *"…seems like, as if it kind of wasn't real…"* 8F

Others described the use of denial, be it conscious or sub conscious in dealing with the trauma of the experience.

> *"…for a long time I was just, well, in denial I think, "oh no, I'll be alright, I'll be alright…"*6M
> *"But when they (thoughts/feelings associated with major PE) come to the surface, well I have puzzles and things which I do to block it out…I don't want to think about it so my puzzles are one way of avoiding thinking about it for me."* 1F

Hyper vigilance

Patients reported increased increased vigilance and awareness of anxiety any symptoms they felt could be associated with a recurrent PE. Such awareness was associated with increased anxiety and catastrophising thought processes.

> *"In the beginning I was very very very weary, very scared. I would only have to get a sort of sign or niggle in my chest and I would start to panic thinking that it was going to happen again or I'd end up in a heap on the floor"*2F

> *"It was always on my mind. It made me more conscious of making sure that if I was on my own somewhere people knew….I taught my daughter nannies house number…just in case something did happen. It just makes me angry to think that no-one can tell me I won't have another one and now I have to live my life by this"*2F

Major theme 3: Support needs

All participants described needing a significant degree of support and it was evident that the support needed was ongoing but differed over time. The nature of support required often required clinical and or specialist knowledge, and appeared to be an unmet need which could only be met by appropriate healthcare professionals.

Information

During the initial stages of diagnosis and treatment, participants required considerable information regarding their condition, their prognosis and long term treatment. Many described their care as focusing on the biomedical with little attention given to support through information giving or psychological care.

> *"None of them actually said anything to make me understand, it was just a case of 'you've had these clots, they've gone to your lungs', none of the rest of what else could have happened before they got to the lungs registered or how serious it was when it got to there."* 5F

Where information was not freely available, participants would seek answers on the Internet. This could result in accessing upsetting information, which ~~form of information gathering,~~ without access to additional support or proved more distressing than helpful.

> *"Yeah after looking on the internet I did the whole sitting, crying, rocking thing thinking 'oh me god' and then told myself off for looking to be honest because finding out that way with no-one there to kind of go through it with me knocked me for six."* M5

Participants were clear on the degree of information they required: frequently describing the need to understand why this had happened to them and what they should/ should not do from then on to rehabilitate effectively.

> *"It causes me quite a lot of concern doing things…and I'm scared of doing them in case it happens again….I just get so annoyed that's that the thing that will stop me, because I worry that if I get a bit out of breath or feel my heart going that I'll end up in a heap on the floor basically…but I wouldn't worry as much if I just knew what was causing it, or someone could tell me how much I can push myself"*

> *"It just annoys me because I just can't achieve what I used to achieve and I just haven't got the answers as to why. Why can't I? What's stopping me? What's making that happen to me? If I had the answers I'd be alright with it. I'd get on with it". 3F*

When basic information was provided, including reaslistic outcomes, partcipants were able to make more sense of their lives and symptoms, describing a more positive rehabilitation.

> *"So I asked if he could provide me with some information about what was the likely cause and some information about what I could expect or hope for really in recovering for me which was quite a fortuitous bit of information that I got which encouraged me a bit but it sort of did seem possible that by just keeping on with the blood thinning that these could eventually get re-absorbed and I could get back to sort of normal activity."* 4M

Empathy

Participants considered themselves to have experienced a narrow escape from death and as described before expressed considerable psychological distress after the event. They did not feel that healthcare professionals fully appreciated the seriousness of their experience and thus did not understand the distress associated with symptoms suggestive of VTE recurrence.

> *"But I cant remember thinking that you know, I might have died, that my daughter might not have had her mum, and no one helping to make sure that I understood what was going on, or what was wrong with me, or how this would effect my life. I just remember feeling quite resentful of the medical staff."* 2F
>
> *"And I did start to panic then and think well you know if I had a pain in the chest again I could be telling someone what I think it is but would they actually take my word for it kind of thing. And I did actually feel that it wasn't really taken too seriously. I mean the fact that it could of killed me and they had a very blasé approach toward it."* 2F

Access to support

Whilst there was a significant requirement for information and support from healthcare professionals, some participants also identified the potential benefits of self-help/ support groups. The opportunity to meet other people who understood their experiences and associated feelings was considered a positive thing and there was a belief that several unmet needs could be provided by fellow PE patients.

> *"I would have loved, and still would like some sort of group thing or support to be available to help me come to terms with what's happened to me…somewhere where somebody could have explained 'yeah its normal to feel like that' etcetera, you know like maybe other people who had been through the same thing. I don't think I would of felt so on my own then…. Just to have this level of conversation with somebody back then would have helped massively. To help me process it all through, because it was very 'off you go' and that was that".* 5M

Discussion

Venous thromboembolism is a common medical condition, which may cause a spectrum of physical symptoms. In its most severe form, major symptomatic pulmonary emboli may lead to cardiovascular compromise and even death. Whilst the long-term complications such as post thrombotic syndrome and pulmonary hypertension are well recognized, little has been known about the psychological impact of symptomatic VTE. In our study of previously healthy adults who experienced a symptomatic pulmonary embolus we have identified that the psychological consequences of experiencing symptomatic VTE are considerable. The development of VTE is considered a life-changing event with some patients feeling a loss of identity and role in life. More concerning appears to be a profound and ongoing collection of symptoms suggestive of the development of PTSD. This is the first time that PTSD has been identified as a consequence of VTE. To some extent these findings shouldn't come as a surprise since features that contribute to the development of PTSD are common in VTE patients; patients of previous good health experience a traumatic life threatening event and the face a future of uncertainty regarding recurrence. However, these findings raise the possibility that as healthcare professionals we are failing to recognise the psychological needs of our patients.

There are several limitations to this study: the number of participants is small and although the numbers are appropriate for such qualitative methodology, a larger study is clearly needed to identify the true prevalence of PTSD using a validated screening tool. In particular it is not possible to identify whether PTSD may be more prevalent is certain sub groups of patients with PE. Within the group sampled the majority were younger than 45 years old and it is possible that the greater degree of psychological distress is seen in younger patients with less illness experience. Likewise PTSD may be more prevalent in those without obvious precipitating cause of VTE since they will live with ongoing uncertainty regarding recurrence. The long term treatment plan may also play a role and it would be interesting to see whether PTSD is more likely to develop in those with ongoing reminders of their illness such as long term anticoagulation.

There is ~~also~~ a possibility of selection bia,s since all participants interviewed had required admission to hospital for their symptomatic PE and as such were likely to be those with more severe symptoms and thus a more traumatic experience. Whilst the likelihood of bias is acknowledged, it shouldn't invalidate the findings in the context of those with the most significant VTE episodes. It would be presumptive to assume that all VTE patients experienced PTSD in the same way that one acknowledges that PTSD occurs in some but not all myocardial infarction patients. It does, however, highlight that of those developing VTE, a subgroup may experience significant psychological sequelae and it would make clinical sense to identify those at greatest risk and arrange appropriate support. At present it is not possible to identify whether the development of PTSD is directly related to the VTE experience or whether there are particular pre morbid characteristics that predispose people. It is of interest to note that participants felt they received limited information and would have liked more opportunities to understand their condition from an appropriately trained professional rather than seek information themselves on the internet.

Finally this study highlights several areas of opportunity for healthcare professionals to deliver support to patients post VTE be it through information giving, empathy or identifying psychological distress early on. It is possible early intervention may reduce the development of long-term psychological distress and the ongoing challenges it brings.

SN affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

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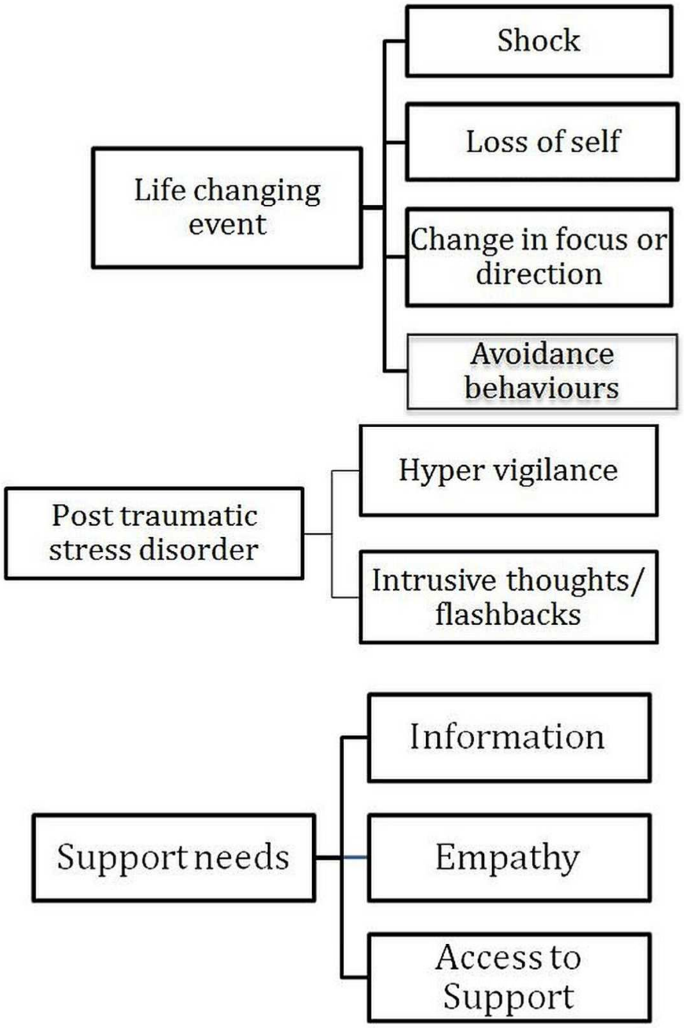

Major themes and associated sub-themes
90x94mm (300 x 300 DPI)

COREC CHECKLIST

All applicable items in the checklist have been addressed within the manuscript. These have been outlined in the comments section of the table below.

No	Item	Guide questions	Comments and page
Domain 1: Research team and reflexivity			
Personal Characteristics			
1.	Interviewer/ facilitator	Which author/s conducted the interview or focus group?	RL and JW
2.	Credentials	What were the researcher's credentials? *E.g. PhD, MD*	MSc students
3.	Occupation	What was their occupation at the time of the study?	MSc students
4.	Gender	Was the researcher male or female?	Female
5.	Experience and training	What experience or training did the researcher have?	Experienced clinical psychologists trained in qualitative research.
Relationship with participants			
6.	Relationship established	Was a relationship established prior to study commencement?	No prior relationship
7.	Participant knowledge of the interviewer	What did the participants know about the researcher? e.*g. personal goals, reasons for doing the research*	No prior knowledge
8.	Interviewer characteristics	What characteristics were reported about the interviewer/facilitator? e.g. *Bias, assumptions, reasons and interests in the research topic*	No stated previous interest in VTE management

Domain 2: study design			
Theoretical framework			
9.	Methodological orientation and Theory	What methodological orientation was stated to underpin the study? *e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis*	Interpretative phenomenological analysis
Participant selection			
10.	Sampling	How were participants selected? *e.g. purposive, convenience, consecutive, snowball*	Sequential screening
11.	Method of approach	How were participants approached? e.*g. face-to-face, telephone, mail, email*	Eleven
12.	Sample size	How many participants were in the study?	Nine
13.	Non-participation	How many people refused to participate or dropped out? Reasons?	Two. No reasons sought
Setting			
14.	Setting of data collection	Where was the data collected? e.*g. home, clinic, workplace*	Clinic
15.	Presence of non-participants	Was anyone else present besides the participants and researchers?	No
16.	Description of sample	What are the important characteristics of the sample? *e.g. demographic data, date*	Given in table 1
Data collection			
17.	Interview	Were questions,	Prompt questions

	guide	prompts, guides provided by the authors? Was it pilot tested?	following pilot testing
18.	Repeat interviews	Were repeat interviews carried out? If yes, how many?	No
19.	Audio/visual recording	Did the research use audio or visual recording to collect the data?	Digital audiorecording
20.	Field notes	Were field notes made during and/or after the interview or focus group?	Field notes were taken
21.	Duration	What was the duration of the interviews or focus group?	Thirty minutes
22.	Data saturation	Was data saturation discussed?	No since we used interpretative phenomenological analysis
23.	Transcripts returned	Were transcripts returned to participants for comment and/or correction?	No
Domain 3: analysis and findingsz			
Data analysis			
24.	Number of data coders	How many data coders coded the data?	Two
25.	Description of the coding tree	Did authors provide a description of the coding tree?	Yes
26.	Derivation of themes	Were themes identified in advance or derived from the data?	Derived from the data
27.	Software	What software, if applicable, was used to manage the data?	Not applicable
28.	Participant checking	Did participants provide feedback on the findings?	No
Reporting			
29.	Quotations presented	Were participant quotations	Yes

		presented to illustrate the themes / findings? Was each quotation identified? e*.g. participant number*	
30.	Data and findings consistent	Was there consistency between the data presented and the findings?	Yes
31.	Clarity of major themes	Were major themes clearly presented in the findings?	Yes
32.	Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	Yes