

WOMEN'S VIEWS AND EXPERIENCES OF A PATIENT PREFERENCE TRIAL IN SURGERY: A QUALITATIVE STUDY OF A PILOT TRIAL COMPARING COLPOSUSPENSION TO ANTERIOR REPAIR & TVT

Hypothesis / aims of study

Surgical trials are difficult to conduct, and although many successful studies are published, recruitment to surgical trials is often slow. The process of counselling and consent is more complex than for drug trials, and it is known that surgeons can be reluctant to relinquish control and accept third party randomisation(1). In 2007 we completed a pilot randomised trial comparing colposuspension with tension free vaginal tape insertion plus anterior vaginal repair(2), which was intended to pilot trial procedures and test feasibility of the trial design. Recruitment to the pilot was very slow. In parallel to the pilot, we completed this parallel qualitative interview study to characterise women's experiences and opinions about taking part.

Study design, materials and methods

All women approached to participate in the pilot RCT were sent an invitation letter explaining the study, with a reply slip addressed directly to the interview team, rather than the main study investigators. Those women who returned the slip were then contacted, the study explained, and a convenient time for the interview arranged.

Interviews focused on women's views and experiences of being invited to take part in the CARPET1 trial. An interview prompt guide, based on review of literature, discussions within the project team and a patient representative, was developed to help structure the interview but was used flexibly to allow participants to construct their accounts on their own terms. The prompt guide was revised and refined throughout the interviewing process in response to emerging themes. Each interview lasted for approximately 45 minutes and was digitally recorded. All tapes were anonymised, transcribed verbatim, and labelled with an identification number only. Analysis was based on the constant comparative method(3) assisted by QSR N6 software. A coding framework was developed through close and repeated inspection of the transcripts, initially to identify textual units of meaning, which were then organised into higher order thematic categories with explicit specifications.

Results

All 56 women who were invited to take part in the pilot trial, including the 25 who declined to take part in the trial, were approached. All 16 women who were interviewed (52% of the pilot trial subjects) had joined the pilot; we could not interview any women who declined participation. Participants were between 38 and 81 years old.

For most women [11] their primary motive for participating in the trial focused on the possibility that they might benefit in some way (e.g. to obtain extra information, a longer follow-up period, and extra care). Most women suggested that these views had originated from the surgeons/recruiters.

Most participants were pleased with the quality of the information and had been able to ask questions and have a full discussion with the doctor. Most [12] acknowledged the principle of equipoise, clearly stating that there was uncertainty over which type of surgery was best. This indicated women's belief in *collective* equipoise in terms of treatment efficacy.

Few women gave an account of randomisation that could be considered consistent with that of researchers. Participants were unsure of the rationale for randomisation, and the role of "the computer" (mentioned on the Patient Information Sheet) in choosing the type of surgery was unclear in most accounts. 5 (correctly) saw computer-generated randomisation in terms of a lottery or throwing a dice, but others [3] reported they had no idea about the role of the computer. Participants tended to have an emotional response to the involvement of computers in making decisions about something as intimate as medical treatment. Some [3] participants appeared uncertain about whether the computer was delivering individualised decisions and determining type of surgery based on information about the patients.

Where women expressed a strong preference for a particular intervention, preference seemed to have little to do with the likelihood of the surgery resolving the prolapse. Rather, the focus of their preference concerned features of the operation as it might affect their own situation. For women who chose TVT, their choice was based on having no cut/scar and a smaller operation with a shorter recovery time. Those who chose colposuspension wanted the surgeon to be able to have a 'proper look around'; to avoid a spinal injection; or to have the prolapse supported by stitches rather than the insertion of a foreign body. Randomisation was only considered by women to be appropriate where both treatment options were equally suitable and the woman had no strong preference.

Though women described feeling in control, it was also clear that decisions both about whether to be randomised and about which treatment to opt for if expressing a preference were strongly influenced by their interactions with the surgeon. Trust in the surgeon was a feature of eight accounts, including both participants who agreed to be randomised. Participants' accounts suggested surgeons acknowledged collective or "academic" equipoise (i.e. the principle that it was not known at a universal level which treatment was best). However, nine women reported that they perceived the doctor as having a preference in their case for a particular surgery, suggesting a lack of *individual* equipoise.

Interpretation of results

These findings suggest that considerable challenges may remain in conducting RCTs in surgery. For women in this study, the patient preference arm of the trial was largely seen as a win-win situation: they could not only choose the treatment that they would have chosen anyway, but they also received the perceived benefits of trial participation in the form of extra care and attention. Though our data suggest that while women may be unwilling to be randomised when given the choice, this does not necessarily mean that they will refuse to participate in a standard RCT because they perceived benefits of trial participation over routine care, regardless of treatment arm.

However, the data also indicate that the main influence on a potential participant's willingness to be randomised is likely to be the recruiting clinician and how s/he presents both the rationale for the trial and information about the treatment arms. Even when women recognise the need for a RCT, they may (understandably) be unwilling to be randomised where they believe that one option may be better than the other for them as individuals. Crucially, clinicians (surgeons in this case) did not appear to women to be in equipoise at the level of the individual patient, despite the pilot recruiting only in the centres of the grant investigators!

The impact of the surgeons' influence on women's choices is unambiguous in their accounts and is unsurprising: rejecting the informed advice of a surgeon would be a peculiar choice in this situation. Persuasive phrases such as "before you decide" and "the way he put it" in women's accounts indicate that the surgeons were the ones who were really in control. It could be argued that CARPET 1 was subconsciously a *surgeon* preference trial.

Concluding message

This is a small study, limited by the number of women who agreed to be recruited both to the trial and the qualitative study. Nonetheless, it offers some important suggestions for future trial design in surgery. Standard RCTs to compare surgical treatments may remain difficult where surgeons have perceived strong preferences about what is the best option for an individual patient, even when there is no strong objective evidence for this. Patient-preference trials, for some types of surgery at least, be more appealing than standard RCTs to surgeons and patients alike, and may offer a means of conducting studies in surgery that might otherwise be infeasible.

References

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<i>Specify source of funding or grant</i>	The study was funded by the Medical Research Council grant G0500251. The application was funded after external peer review. The study was sponsored by University Hospitals of Leicester NHS Trust. The study sponsor and the funder were not involved in the study design and the collection, analysis, and interpretation of data, and the writing of the article and the decision to submit it for publication.
<i>Is this a clinical trial?</i>	Yes
<i>Is this study registered in a public clinical trials registry?</i>	Yes
<i>Specify Name of Public Registry, Registration Number</i>	The protocol was registered on Current Controlled Trials in May 2006 (http://www.controlled-trials.com/ISRCTN34759911) and was added to the MRCs meta-Register of clinical trials (http://www.controlled-trials.com/mrct/trial/183403/carpet).
<i>Is this a Randomised Controlled Trial (RCT)?</i>	Yes
<i>What were the subjects in the study?</i>	HUMAN
<i>Was this study approved by an ethics committee?</i>	Yes
<i>Specify Name of Ethics Committee</i>	The study was approved by the Leicestershire, Northamptonshire and Rutland Research Ethics Committee One
<i>Was the Declaration of Helsinki followed?</i>	Yes
<i>Was informed consent obtained from the patients?</i>	Yes