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# SYNTHETIC MESH FOR PROLAPSE REPAIR: DO WOMEN WANT IT?

## Hypothesis / aims of study

The standard vaginal repair for pelvic organ prolapse has a recognised recurrence rate and the use of synthetic mesh as an alternative to standard repair has an associated complication rate associated with the mesh. Despite the lack of good quality long term data to support their use, meshes are widely used for both primary and secondary prolapse surgery. This study aims to assess womens' expectations as to the outcome of surgery and to determine their perception of synthetic mesh use in the surgical management of their prolapse.

# Study design, materials and methods

Women were recruited from those attending the urogynaecology and urodynamics outpatient clinics presenting with symptomatic prolapse and seeking a surgical solution to their complaint. A urogynaecological history was obtained and the degree of their prolapse was determined by clinical examination and categorised into mild, moderate and severe. Women were then asked to complete a 18 question multiple choice questionnaire which determined the degree of bother of their prolapse, their expectations of success rate of any surgical procedure for their prolapse after 1, 5 and 10 years, and the degree of complications of mesh repair that they were willing to accept. The final part of the questionnaire gave women the current evidence for the success rate of both procedures and the complications of synthetic mesh and asked women to choose their preferred method of repair. Women completed the questionnaire anonymously in the clinic setting but without assistance or prompting and handed the completed questionnaire back before leaving. No questionnaires were posted at a later time. Women unable to speak or read English or who were unable to complete the questionnaire for other reasons were excluded from the study. Women without clinically demonstrable vaginal prolapse were also excluded from the study.

#### Results

96 women completed the questionnaire. The mean age was 62 years (46-77). Of the women who completed the questionnaire, 63/96 (66%) had never had previous prolapse surgery, 33/96 (34%) had previously undergone one or more surgical procedures for prolapse. No women had previously undergone synthetic mesh repair. The prolapse severity of the women who participated is shown in table 1.

Table 1: Distribution of prolapse severity in women (n=96)

|                 | None | Mild | Moderate | Severe |
|-----------------|------|------|----------|--------|
| Cystocoele      | 8    | 21   | 40       | 26     |
| Uterine descent | 11   | 24   | 55       | 6      |
| Rectocoele      | 6    | 26   | 50       | 14     |

<u>Table 2</u> shows the distribution of the acceptable recurrence rate of surgery for prolapse indicated by women at 1, 5 and 10 years after surgery (n=96)

| Acceptable<br>Recurrence<br>Rate | 5%       | 10%      | 20%             | 30%             | 50%      | >50%   |
|----------------------------------|----------|----------|-----------------|-----------------|----------|--------|
| At 1 year post op                | 11 (11%) | 33 (34%) | 40 (42%)        | 12 (13%)        | 0        | 0      |
| At 5 years post op               | 4 (4%)   | 20 (21%) | <u>28 (29%)</u> | 30 (31%)        | 13 (14%) | 1 (1%) |
| At 10 years post op              | 3 (3%)   | 13 (14%) | 29 (30%)        | <u>35 (36%)</u> | 10 (10%) | 6 (6%) |

<u>Table 3</u> indicates the acceptable rates of complications associated with mesh repair that women were willing to accept to undergo mesh repair (n=96)

| Complication    | <1%             | 5%              | 10%             | 20%      | 30% or   |
|-----------------|-----------------|-----------------|-----------------|----------|----------|
| rate            |                 |                 |                 |          | more     |
| Vaginal Pain    | 32 (33%)        | <u>45 (47%)</u> | 15 (16%)        | 4 (4%)   | 0        |
| Vaginal Mesh    | 17 (18%)        | 63 (66%)        | 14 (15%)        | 2 (2%)   | 0        |
| Exposure        |                 |                 |                 |          |          |
| Pain during     | 21 (22%)        | 24 (25%)        | <u>25 (26%)</u> | 15 (16%) | 11 (11%) |
| sexual          |                 |                 |                 |          |          |
| intercourse     |                 |                 |                 |          |          |
| Serious         | <u>68 (71%)</u> | 27 (28%)        | 1 (1%)          | 0        | 0        |
| complications   |                 |                 |                 |          |          |
| such as erosion |                 |                 |                 |          |          |
| into            |                 |                 |                 |          |          |
| bladder/bowel   |                 |                 |                 |          |          |

When provided with the recurrence rate for prolapse after 1 year with both the standard repair and mesh repair 29/96 (30%) women would choose to have mesh repair. Of the women who had not previously had prolapse surgery 14/63 (22%) would choose to have mesh repair and of the women that had previously had prolapse surgery 25/33 (75%) would choose mesh

repair. When given 5 year recurrence rates after standard repair and informed of the lack of available data for mesh repair: 42/96 (44%) women would choose mesh repair and of women who had previous prolapse surgery 23/33 (70%) would choose mesh repair. When told of the risk of mesh exposure in the vagina of approximately 10%, 26/96 (28%) women would choose to have the mesh repair and given this information, of the women who had previous repair, 18/33 (55%) would have mesh repair. When told of the risks of pain during sexual intercourse and pain in the vagina associated with mesh insertion, 31/96 (32%) women would undergo mesh repair, and 16/33 (48%) of women who had previously had the standard repair would now undergo mesh repair. When asked if they would prefer the a procedure that carried a higher rate of recurrence or a higher rate of complications 76/96 (79%) women indicated that they would prefer a higher risk of recurrence. After completing the questionnaire, and considering the information they had been given, 27/96 (28%) women indicated that they would elect to have mesh repair, and 18/33 (54%) of women who had previous standard repair would choose to have mesh repair.

# Interpretation of results

Women's expectation of the surgery success is not as high as expected. 44% would find a 30% or more risk of recurrence after 5 years as acceptable and 52% consider the same recurrence rate after 10 years to be acceptable. Women do have high expectations about the low complications of mesh surgery. Thirty three per cent of women expect the risk of vaginal pain to be 1% or less and 84% expect the risk of mesh exposure to be 5% or less. Similarly, 71% of women expect a risk of serious complications to be 1% or less. When given the actual recurrence rates women who have had previous repairs are more likely to choose mesh repair. However, when considering the complications of mesh the proportion of women in this subgroup who would choose to undergo mesh falls. Overall a small minority of women who have never had surgical treatment for their prolapse and only a slight majority (54%) of those who have had surgery would choose mesh repair.

## Concluding message

Before offering mesh repair as a surgical treatment to women, the clinician should explain the associated complications of mesh, and the recurrence rates associated with standard repair as well as the lack of long term data on outcome of mesh repair. The choice of procedure should then be determined by the patient.

| Specify source of funding or grant               | Imperial College Healthcare NHS Trust |
|--|---------------------------------------|
| Is this a clinical trial?                        | No                                    |
| What were the subjects in the study?             | HUMAN                                 |
| Was this study approved by an ethics committee?  | Yes                                   |
| Specify Name of Ethics Committee                 | St. Marys LREC                        |
| Was the Declaration of Helsinki followed?        | Yes                                   |
| Was informed consent obtained from the patients? | Yes                                   |