Commentary on NHS Digital. *Retrospective Review of Surgery for Urogynaecological Prolapse and Stress Incontinence using Tape or Mesh,* April 2018

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1. This review of the use and outcome of procedures for stress urinary incontinence (SUI) and urogynaecological prolapse by NHS Digital was a pragmatic response to the need for a rapid assessment. As such it provides a useful account of what can be gleaned from routine administrative data (Hospital Episode Statistics; HES). As the authors acknowledge, these data are not collected for patient-level analysis so cannot be expected to provide accurate estimates of the effectiveness (benefits) and safety (adverse outcomes, complications) of surgery. They do, however, provide some helpful insights into how the rates of surgery have changed over time and some surrogate indications of outcome (rates of removal of tape and mesh; rates of post-operative out-patient attendance).

2. In summary, the review demonstrated that between 2008/9 and 2016/17:

- The rate of surgery (all types of procedures) for SUI and prolapse fell by 32%
- The rate of tape procedures for SUI fell by 48% and of mesh procedures for prolapse by 13%
- The rate of removal of tape for SUI within 30 days was 1.2-1.7 per 1000 women but was higher in the year after the year of insertion (7-10 per 1000)
- Removal of mesh for prolapse within 30 days was rare but was 2-4 per 1000 in the subsequent year

These data provide only limited insight into the adverse effects of tape and mesh. Removal of implants probably represents only some of those women who suffered moderate or severe adverse effects. The true incidence of problems cannot be determined from HES.

3. Reviewing the data on which the report is based, some further insights either can or could be gained from HES data.

i. Serious adverse effects of tape and mesh could be investigated further by looking at post-operative admissions (by linking to data on subsequent admissions). In addition, mortality could be investigated as HES data can be linked to ONS mortality data.

ii. Removal of implants persists over time. As the Table below for tape procedures for SUI shows, although the highest rates of removal are in the first 24 months, removals continue until at least eight years after surgery (and maybe for longer but those data are not yet available). It appears that after four years the risk of removal reaches a steady rate of about 2.0-2.5 per 1000.

The accuracy of these estimates is vulnerable to several shortcomings in the HES data. The incidence of removals may be an over-estimate as the numerator may include women who are excluded from the denominator because the insertion procedure was carried out in hospitals outside England, in independent hospitals (privately funded) and in NHS-funded patients in independent hospitals (which historically have been found, in joint replacement surgery, to not report activity to HES). Conversely, the removal rate may be under-estimated as such procedures may not be correctly coded. Whether, overall, the data used in the Review has over or underestimated the removal rate cannot be determined.

Remembering that caveat, the data in the Table suggest the accumulated removal rate over 8 years is about 4%. In comparison, a recent analysis of the same data reported 9.8% of women had complications in the first five years and 5.9% were readmitted (Keltie et al 2017). These are consistent with an 8 year accumulated removal rate of 4% as the authors analysis was weighted towards the earlier post-insertion years when removal rates are highest and not all readmissions are for removal of the implant. The implications of these findings for any future auditing are discussed below.

Time of removal of tape for SUI	Number of tape procedures for which data available	Number of removals	Removal rate per 1000 women
Year of insertion	100516	847	8.4
1 year after	93271	957	10.3
2 years after	85342	452	5.2
3 years after	75736	257	3.4
4 years after	63950	194	3.0
5 years after	52086	126	2.4
6 years after	39282	81	2.1
7 years after	26006	63	2.4
8 years after	12327	25	2.0

iii. The overall decline in surgical rates (for SUI and prolapse) between 2008/9 and 2016/17 of 4% a year masks the significant change in practice that took place in 2013/14. Up until then the decline was modest at 1.1% a year. The rate of decline then accelerated to 9.3% a year. The reason for such a sudden change in 2014 is unclear.

The largest reductions were observed for tape procedures for SUI (50% fall) though declines also occurred for mesh procedures (13%) and for colporrhaphy without synthetic implants (12%).

iv. It is difficult to interpret changes in the post-operative out-patient attendance rates particularly as that may simply reflect the completeness and quality of such data. In addition, attendances will reflect not only clinical need (adverse effects of surgery) but also surgeons' judgements as to the appropriateness of routine follow-up and GPs' propensity to refer. Thus, the observed increase between 2008/9 and 2016/17 in the proportion of women attending gynaecological OPs during the post-operative period (from 34% to 60% following tape procedures; from 43% to 65% following mesh procedures) are as likely to be determined by changes in clinicians' policies as by changes in post-operative morbidity. It is interesting to note that over this same period attendances following colporrhaphy also rose (26% to 55%). These data, therefore, provide little evidence about the risks and benefits of surgery.

Similarly, the lack of increase in attendances at pain management OPs (5-7% for all procedures and all years) given widely reported concerns about post-operative pain after tape and mesh implants, may reflect the limited availability of such services or referral practices of GPs and surgeons rather than no increase in the incidence of painful complications.

4. Conclusions that can be drawn from the NHS Digital Review

HES provides only limited insight into the extent of adverse effects of surgery. Revision surgery to remove synthetic implants confirms that some patients suffer adverse effects but does not provide a reliable measure of the incidence or severity of such problems. The decision to remove mesh or tape will depend not only on the severity of the problem a patient experiences but also the action they take to seek further help (which in turn will depend on many factors related to their personal characteristics and their access to the health care system) and the judgement of the surgeon (including their view of a patient's symptoms and whether they think those symptoms can be attributed to the previous surgery).

Reductions in the rate of surgery for SUI and prolapse (and procedures involving mesh and tape in particular) since 2014 could have arisen from either clinicians' doubts about the value of these procedures, patients' doubts, or both. It is unclear what is responsible for this significant change.

Overall, the NHS Digital Review findings are consistent with many studies (both randomised controlled trials and observational studies) in confirming that some women will experience adverse effects of mesh and tape implants to the extent that removal is necessary. The scale of any problems cannot be accurately determined.

5. Recommendations

i. While evaluative studies, including randomised trials, will continue to be performed worldwide and these will help refine the estimates of the benefits and the risk of adverse outcomes of mesh and

tape procedures, there is an immediate need for routine rigorous auditing of these procedures in England.

ii. The British Society of Urogynaecology's audit of surgery for SUI, which commenced in 2013, has established a sound basis for collecting data on all such procedures so the benefits and risks in normal clinical practice (rather than in research studies) can be assessed.

The audit provides information on the numbers of cases, procedure undertaken, complications within 30 days, and patient reported outcomes after three months. This allows the outcomes of different surgeons, hospitals and trusts to be compared.

These are welcome developments that will provide more detailed and higher quality clinical data (eg information on patients' comorbidity) than HES can achieve. However, as is clear from many patients' reports and from the HES data, severe problems with mesh and tape necessitating removal occur well beyond the initial post-operative period covered by the audit.

To understand the true extent of problems that patients experience, the BSUG audit needs to be extended to following up all patients for at least two years. HES data suggests that such a period might capture a high proportion of instances of severe problems (maybe about two-thirds). Longer follow-up would be desirable but the practical problems and cost of keeping in touch with all patients for a more prolonged period so as to achieve a high response rate would be formidable.

An audit extended to two years would allow an exploration of whether the outcome, in particular adverse effects necessitating removal, are associated with any characteristics of the patients (eg age, comorbidity), the procedure (eg brand of tape) or the provider (eg surgeon, hospital). This information would enable potential patients to receive sufficiently detailed information to be able to make an informed decision about their treatment.

The establishment by BSUG of a separate register of removal operations was launched in March 2018. While this will provide useful information on the clinical histories of the women, by design it is limited to those with adverse outcomes who decide to undergo removal surgery. It will not provide any information on those women who suffer complications but do not undergo removal of the implant.

Finally, given that the BSUG Audit is confined to the treatment of SUI, an extension to include surgery for prolapse is needed if the risks and benefits of mesh procedures are to be assessed routinely.

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Reference

Keltie K, Elneil S, Monga A, Patrick H, Powell J, Campbell B et al. Complications following vaginal mesh procedures for stress incontinence: an 8 year study. Scientific Reports 2017,7,12015.