



Autonomy Vs Justice – Outcome from the UK mesh pause.

Hypothesis/Aims of Study

The UK government and NHS have put on hold the use of vaginally inserted **surgical mesh** for stress urinary incontinence (SUI) since July 2018, following a recommendation by the Independent Medicines and Medical Devices Safety Review. This hold on treatment will be in place for the foreseeable future to ensure that patients receive a safe and high-quality care.

As a consequence of this recommendation, the number of TVT - TOT inserted in patients has greatly reduced. With the exception of a few centres in the whole UK. In April 2019 a new NICE guideline recommended that all options should be offered to the patient for the management of SUI, including TVT. Despite this there is still a surgical pause in place. We hypothesised that as a consequence of this measure a number of patients have continued to suffer from SUI rather than having alternative surgical treatment. We hypothesised that the surgical pause is impacting patients' autonomy.

Study design, materials and methods

This is a combined retrospective data analysis and telephone questionnaire carried on in a 2-year care hospital. We used to insert TVT and TOT for the management of SUI, but currently are being affected by the surgical pause.

We collected the total number of TVT -TOT undertaken for a period of 1 year prior to the MESH ban and compared them with the numbers after the ban. We looked at the numbers of referrals to tertiary centre for alternative surgical management. We also identified those patients who were eligible for surgical option but opted not to be referred. We contacted them and asked the followings:

- 1 - Have you had surgical treatment?
- 2- Reasons for opting out of the surgical option?
- 3 - Would they be happy to undergo TVT surgery?

Results

Pre surgical pause - From June 2017 to June 2018

- Mesh incontinence procedures undertaken = 45 patients

Post-surgical pause - From August 2018 to August 2019

- Mesh incontinence procedure undertaken = 0 patients
- Incontinence surgery referral to tertiary centre = 15 patients
- Declined referral to tertiary centre = 30 patients
 - Interviewed patients = 25
 - Not available for interview = 5 patients
- Answers to telephone questions



- 1 - Have undergone surgery at a later date = 5 patients
- 2 - Reason for opting not to have surgery –
 - 15 patients thought that the alternative to TVT/TOT were more complex and risky surgeries, so they preferred to manage their incontinence conservatively.
 - 5 could not provide a specific answer.
- 3 - Would they be happy to have TVT/TOT?
 - 18 patients answered yes.
 - 2 patients answered no.

Concluding message

Justice and safety are key drivers in socialised medicine like the one practised in the UK. In our sample we found out that Autonomy and patient's choice have been affected in 18 out of 20 cases. Despite the best available evidence, we think that sometimes politics and lobbying groups may prevail over scientific evidence and patient's choice. In our example patient's autonomy has been affected.