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COMPLICATIONS OF MESH KITS FOR PELVIC ORGAN PROLAPSE: A REVIEW OF MANUFACTURER AND USER FACILITY DEVICE EXPERIENCE (MAUDE) DATABASES

Hypothesis / aims of study:
Mesh kits are increasingly being used in pelvic organ prolapse surgery. Whilst published studies report reassuring results (1), little is known about complications experienced outside the research setting. Search of the US Food and Drug Administration Manufacturer and User Facility Device Experience (MAUDE) databases has been shown to provide more insight into complications associated with using other devices, such as midurethral slings (2). Whilst it is recognised that such search does not provide an accurate estimation of the incidence of complications, as the total number of devices used is not available, nor compare the safety of different kits, as possible confounding factors are not recorded, it can give additional information about the type and scope of such complications.
The aim of this study was to evaluate the nature and seriousness of complications associated with using mesh kits for pelvic organ prolapse surgery as recorded in the US Food and Drug Administration Manufacturer and User Facility Device Experience (MAUDE) databases.

Study design, materials and methods:
The US Food and Drug Administration Manufacturer and User Facility Device Experience (MAUDE) databases were searched for complications associated with the use of Prolift ®, Avaulta ®, as well as Perigee ® and Apogee ® from 2005 to 2008. Complications related to the same patient were entered only once.Collected data included type of mesh used, nature of complication(s), management and source of report.

Results:
A total of 203 patients reported to have had complications were between the three mesh kits used, as shown in table 1. The distribution of complications is shown in table 2. Erosion was the most frequent one, followed by pain and dyspareunia, which led to martial discord in one case. Serious complications, like undetected rectal perforation that led to septicaemia and multi-organ failure, bowel and urinary fistulae as well as major vascular injury were noted. These complications are seldom reported in literature. The Distribution of management actions followed in dealing with the reported complications is shown in table 3. Mesh excision, partial or total, was the most frequent management approach, which was repeated in some patients. Conservative measures like antibiotics and local oestrogen cream, were also followed. Major surgery like laparotomy and ureteric re-implantation were also described. The distribution of complicated cases by the reporting source is shown in table 4. Manufacturers and those related to them reported the majority of cases.

Location of mesh kit	Avaulta ®	Perigee ® / Apogee ®	Prolift ®	Total
Anterior	29	24	12	65
Posterior	33	21	2	65
Total (Prolift)	N/A	N/A	19	19
Anterior and posterior	19	13	6	38
Unrecorded	2	0	23	25
Total	83	58	62	203

Table 1: The distribution of reported complicated cases according to the type of mesh used.

Complication	Avaulta ®	Perigee ® / Apogee ®	Prolift ®	Total
Mesh erosion	49	26	33	108
Bladder perforation	5	0	1	6
Rectal perforation	4	4	2	10
Infection / abscess formation	19	5	4	28
Urinary fistula	4	2	2	8
Bowel fistula	1	0	2	3
Prolapse recurrence	1	3	9	13
Pain	27	21	13	61
Dyspareunia	6	13	10	29
Ureteric injury	1	1	2	4
Haematoma	1	2	1	4
Mesh breaking during insertion	2	1	0	3
Septicaemia	1	2	0	3
Necrotising fascitis	0	0	1	1

Table 2: The distribution of reported complications by mesh type.

Management	Avaulta ®	Perigee ® / Apogee ®	Prolift ®	Total
Mesh excision (partial / total)	44	25	35	104
Drainage of abscess	7	3	0	10
Antibiotics	11	0	10	21
Local oestrogen	13	0	7	20
Laparotomy	1	4	3	8
Ureteric surgery	2	1	3	6
Internal iliac artery ligation	0	0	1	1

Table 3: The distribution of management actions by mesh type.

Reporter	Avaulta ®	Perigee ® / Apogee ®	Prolift ®
Manufacturer	58	36	56
Voluntary	16	21	5
Distributer	5	0	0
Company representative	1	0	0
User facility	1	1	1
Not recorded	2	0	0

Table 4: The distribution of reported complicated cases by source of report.

Interpretation of results

More serious complications are being reported the US Food and Drug Administration Manufacturer and User Facility Device Experience (MAUDE) databases than in literature. Pain appears to be a prominent complication and there are life threatening ones as well. Both surgical as well as conservative measures are being followed in dealing with mesh kit complications. Some patients required major surgery involving the ureters and major blood vessels and some required repeat operations, mainly to remove more of the mesh. Most reports are coming from industry, which is a healthy feature.

Concluding message

The use of mesh kit in pelvic organ prolapse is associated with more complications than reported in research trials. This calls for careful patient selection and counselling, monitoring of outcomes as well as for robust studies to assess its impact in day to day clinical practice, as recommended by the National Institute for Health and Clinical Excellence (3).

References

1. BJOG 116: 15-24
2. Neurourology & Urodynamics 26: 46-52
3. NICE Interventional procedure guidance 267

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What were the subjects in the study?	**NONE**