



Sacro-colpopexy using mesh to repair vaginal vault prolapse

Osama M Warda MD

Prof. of Obstetrics & Gynecology

Mansoura University

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RECOMMENDATIONS-I

- Current evidence on the **safety** of sacro-colpopexy using mesh to repair vaginal vault prolapse shows there are serious but well-recognized safety concerns.
- The evidence on **efficacy** is adequate in quantity and quality. Therefore, this procedure can be used provided that standard arrangements are in place for clinical governance, consent and audit.



RECOMMENDATIONS-2

During the **consent** process, clinicians should ensure patients understand that there is a risk of vaginal vault prolapse happening again, and of potentially serious complications, including *mesh erosion (for example, into the vagina)*. Patients should be provided with clear written information about the procedure and its complications.



RECOMMENDATIONS-3

- *Patient selection and treatment* should only be done by clinicians **specializing** in the management of pelvic organ prolapse and urinary incontinence in women.
- All clinicians doing this procedure should have specific up-to-date training and do the procedure regularly.



RECOMMENDATIONS-4

Clinicians should enter details about all patients having sacro-colpopexy using mesh to repair vaginal vault prolapse onto an appropriate registry.

All adverse events involving the medical devices (including mesh) used in this procedure should be reported to the Medicines and Healthcare products Regulatory Agency.



INDICATIONS & CURRENT TREATMENT

1. Vaginal vault prolapse is when the upper part of the vagina descends from its usual position, sometimes out through the vaginal opening. **It is common after hysterectomy** and can affect quality of life by causing pressure and discomfort, and by its effect on urinary, bowel and sexual function.



INDICATIONS & CURRENT TREATMENT

2-Treatment is rarely indicated if there are no symptoms. Mild-to-moderate prolapse may be treated with conservative measures such as pelvic floor muscle training, electrical stimulation and biofeedback. Topical oestrogens and mechanical measures such as pessaries may also be used. Surgery may be needed when the prolapse is severe. Different surgical procedures are available for repairing vaginal vault prolapse using vaginal or abdominal (open, laparoscopic or robotic) approaches. Some procedures involve using mesh to provide additional support.



THE PROCEDURE

I. *Sacro-colpo-pexy using mesh* to repair vaginal vault prolapse is done with the patient under general anesthesia, using an open or laparoscopic abdominal approach. Mesh is attached to the *longitudinal ligament of the sacrum*, or *to the sacrum itself, most often at the level of the sacral promontory*. The mesh is then attached to the apex of the vagina and sometimes to the anterior or posterior vaginal wall.



THE PROCEDURE

2- The procedure can be *combined with surgery for stress urinary incontinence, such as colposuspension or sub-urethral sling placement.* Several different types of meshes or grafts have been used for this procedure, including **synthetic meshes**, **allografts** and **xenografts**. Different types of mesh may have different safety profiles.



EFFICACY

- I-1. Sacrocolpopexy (SCP) had a statistically significantly *lower rate of subjective failure* than vaginal procedures.
- I-2. The use of **mesh** or **biological graft** for SCP **did not affect** the subjective failure rate.
- I-3. Adding colposuspension to SCP did not alter subjective failure rate in a 7-year follow-up study.



EFFICACY

2-1. SCP was associated with statistically significantly *less recurrent prolapse* than vaginal procedures at 1 to 2-year follow-up

2-2. The use of mesh or biological graft **did not affect** the incidence of recurrent prolapse. Recurrent prolapse was not statistically significantly different between SCP and robot-assisted sacrocolpopexy (RASC) when compared with laparoscopic sacrocolpopexy (LSC).

2-3. Adding **colposuspension** to SCP **did not** alter the incidence of recurrent prolapse.



EFFICACY

3. *Anterior compartment prolapse* was statistically significantly **less frequent** in women treated by SCP than in women treated by vaginal procedures.
4. *Apical compartment prolapse* was statistically significantly **less frequent** in women treated by SCP than in women treated by vaginal procedures.
5. *Posterior compartment prolapse* was statistically significantly **less frequent** in women treated by SCP than in women treated by vaginal procedures.



EFFICACY

6. There was **no** statistically significant difference in **quality of life** measured by different types of questionnaires between women treated by SCP and those with vaginal procedures.



EFFICACY

7	.SYMPTOM	AFTER SURGERY (40 months)
A.	Constipation	Increased (from 7% to 13%)
B.	Obstructed defecation	Increased (from 1% to 6%)
C.	Urgency	Increased (from 0% to 2%)
D.	Pelvic pressure symptoms	Reduced (from 67% to 9%)
E.	false urge to defaecate	Reduced (from 51% to 5%)
F.	Dyspareunia	Reduced (VSC> SCP)



SAFETY

DEATH & INTENSIVE CARE ADMISSIONS

1. Incidence of **death** was **not** statistically significantly different between women treated by abdominal sacrocolpopexy (SCP) using mesh (0/503) and women treated using native tissue.

2. Postoperative **admission to intensive care** was not statistically significantly different between the SCP using mesh group and the native tissue repair group



SAFETY

3. DVT & PULMONARY EMBOLISM:

Deep vein thrombosis or pulmonary embolism was **not** statistically significantly different between the SCP using mesh group and the native tissue repair group.



SAFETY

4. MESH COMPLICATIONS

- A. *Mesh or suture complications* were statistically **significantly more frequent** in women treated by SCP using mesh than in women who had native tissue repair.
- B. *Mesh erosion* was **not** statistically significantly different between robot-assisted sacrocolpopexy (RASC) and laparoscopic sacrocolpopexy.
- C. *Mesh erosion* was statistically significantly **lower** in women treated by RASC with supracervical hysterectomy than in women treated by RASC after total hysterectomy.
- D. *Mesh erosion* was reported in **1% of women treated by LSC at 12 months** and in 3% at 60 months in a prospective case series of 101 women.



SAFETY

5. Reoperation rates were similar for women treated by SCP or sacrospinous ligament fixation with follow-up of 6 to 66 months.

6. The vaginotomy rate in women treated by RASC was 1% (14/1,488) in the systematic review and meta-analysis of 1,488 women from 27 studies.



SAFETY

7. Urinary tract injury was (2%) in women treated by SCP using mesh compared with (1%) in women treated by native tissue repair . Bladder injury in women treated by RASC was 2% . Ureteral injury was less than 1% in women from the same systematic review.

8. Bowel injury in women treated by RASC was less than 1%.



SAFETY

9. **Stress incontinence** in women who had not had it before and who were treated by LSC was 24% and 38% at 12 and 60 months respectively.. **Postoperative voiding disorders** occurred in 8% and 13% of women at 12 and 60 months respectively. . **Urge incontinence** in women who had not had it before occurred in 2% women at 12 months and in 8% at 60 months. **The detrusor muscle overactivity rate was 9%).**



SAFETY

10. Dyspareunia was statistically significantly **lower** in women treated by SCP using mesh (5%) than in women treated by native tissue repair (12%) .The rate of dyspareunia was similar for SCP using mesh (12) and native tissue repair (9) in another study. Dyspareunia in women who had **not** had this before who were treated by LSC was 2% and 24% at 12 and 60 months respectively in the prospective case series of 101 women.



SAFETY

11. Rectocele and cystocele incidence in women who had **not** had these before and who were treated by LSC was (12%) and 8% respectively at 8-year follow-up in the case series of 165 women.



SAFETY

I2. Infection rates were **not** statistically significantly different between women treated by SCP using mesh (3%) and women treated by native tissue repair (1%). **Abscess formation** in women treated by RASC was less than 1%). **Peritonitis** caused by bowel injury was reported in less than 1% (2/1,118) of women in the same review.



SAFETY

I 3. Bleeding rates were **not** statistically significantly different between women treated by SCP using mesh (3%) and women treated by native tissue repair (2%).

I 4. Ileus or small bowel obstruction was statistically significantly **higher** in women treated by SCP using mesh (2%) than in women treated by native tissue repair (less than 1%). **Bowel obstruction** in women treated by RASC was less than 1%.. **Postoperative constipation** in women treated by LSC was 1% and 5% at 12 and 60 months respectively.



SAFETY

15. Lumbosciatica pain was reported in 3% of women treated by LSC in the case series of 165 women.

16. Intraoperative complication rates were **not** statistically significantly different between women treated by RASC and women treated by LSC . *The incidence of all* postoperative complications was **not** statistically significant between RASC and LSC and this was also true for **severe** postoperative complications (of grade 3 or higher).



Conclusion

- Current evidence on the **safety** of sacro-colpopexy using mesh to repair vaginal vault prolapse shows there are serious but well-recognized safety concerns.
- The evidence on **efficacy** is adequate in quantity and quality. Therefore, this procedure can be used provided that standard arrangements are in place for clinical governance, consent and audit.
- Although RASC requires more cost, it seems not superior to LSC regarding results, and safety.
- SCP using mesh has superior results to SCP using native tissue, nevertheless, has slightly higher drawbacks (refer to safety)



THANKS