National Institute for Health and Care Excellence

IP 379/2 Laparoscopic cerclage for cervical incompetence to prevent late miscarriage or preterm birth

IPAC date: 8 November 2018

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1	Consultee 1 British Maternal & Fetal Medicine Society	**General**	Thank you for giving BMFMS the opportunity to comment on this NICE operational guidance Overall I think this is a useful paper that describes that laparoscopic cervical cerclage is a potentially acceptable approach to the management of recurrent midtrimester loss resistant to transvaginal cerclage. There are a number of comments We would wish to make. Primarily this guidance does not help the clinician in deciding whether to do a an interval or early pregnancy cerclage nor does it help decide if laparoscopic or open cerclage is preferable. The only randomised study that I am aware of between abdominal and transvaginal cerclage is the MAVERIC study which has not been referenced (though it has been mentioned in one of the specialist reviews)	Thank you for your comment. The NICE Interventional Procedures programme assesses the safety and efficacy of new interventional procedures. The Committee makes recommendations on conditions for the safe use of a procedure including training standards, consent, audit and clinical governance. It does not have a remit to determine the placement of a procedure in the pathway of care for a disease or condition. There is a committee comment noting that there is uncertainty about the optimal timing of the procedure. The Interventional Procedures Programme team was advised that there were no laparoscopic procedures included in the MAVRIC study.
2	Consultee 1	**General**	The comparative data in the tables is not comparative as the groups are not matched	Thank you for your comment.

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	British Maternal & Fetal Medicine Society			The overview notes that some of the studies compare post-procedural obstetric outcomes with pre-procedural ones.
3	Consultee 1 British Maternal & Fetal Medicine Society	**1.2**	There is no reasoning behind the make up of the MDT performing patient selection. This team should include an obstetrician/gynaecologist with experience in the management and prevention of preterm delivery and a clinician with experience in all the methods of cerclage being considered (experience is particularly necessary if laparoscopic or robotic cerclage is being considered).	Thank you for your comment. Section 1.2 of the guidance has been changed.
4	Consultee 1 British Maternal & Fetal Medicine Society	**2**	The guideline mentions removal of the cerclage at 37 weeks after vaginal procedures, it then mentions that after an abdominal procedure that you need to do a CS. There is no mention of removing OR NOT the suture that has been inserted abdominally. There might also be some merit in the guidance including how also to deal with other issues during pregnancy with abdo cerclage. The references include the TOG article (Gibb D, Saridogan E. [2016]) which had practical advice about how to deal with non-viable pregnancies, etc. It may be that they consider this to be outside the scope of this guidance. The guideline seems only to cover cerclage for recurrent pregnancy loss and not post-trachelectomy.	Thank you for your comment. Section 2 of the guidance has been changed to include '*The suture may be left in place for subsequent pregnancies*.' Guidance about how to deal with non-viable pregnancies is outside the scope of this guidance. Evidence on patients with trachelectomy has been included in the overview.
5	Consultee 1 British Maternal & Fetal Medicine Society	**Safety summary in overview**	There is very little in this guidance on the adverse outcomes associated with cerclage including uterine rupture (if labour ensues when the suture is in situ) and no description of the complications associated with open cerclage	Thank you for your comment. Safety outcomes that were described in the published literature are summarised in the overview. Uterine rupture after laparoscopic cerclage was not identified in the published literature.

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				A committee comment has been added to the guidance, stating that the committee was informed of the risk of uterine rupture. It is not within the remit of the guidance to describe complications associated with open cerclage, other than those described in the comparative studies.
6	Consultee 1 British Maternal & Fetal Medicine Society	**General**	This guidance should include the need for randomised studies comparing timing and type of trans abdominal cerclage	Thank you for your comment. There is a committee comment noting that there is uncertainty about the optimal timing of the procedure. The aim of the guidance is to assess the safety and efficacy of laparoscopic cerclage.
7	Consultee 2 BSGE	**General**	BSGE's comments have already been made by our members in an individual capacity and that we do not have any further comments to add.	Thank you for your comment.

"Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees."

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