

Have the safety concerns about laparoscopic hysterectomy been fully addressed?

Sir,

One wonders about the way forward after reading the paper by Donnez *et al.*¹ and the accompanying editorial by Garry² in the March 2009 issue of the BJOG. Do we need any further evidence to dispel our lingering doubt about the safety of laparoscopic hysterectomy? Garry's² RCT (randomized controlled trial) was carried out in the UK in the 1990s. Gynaecologists who participated in the eVALUATE study performed on an average five laparoscopic hysterectomies in a year. Understandably, their risks of major complications were significantly higher than Donnez's team that has carried out on an average 200 laparoscopic hysterectomies per year. Donnez *et al.*¹ has quoted paper by Bojahr *et al.*³ in support of the safety of the laparoscopic approach. However, all of these studies are retrospective and by their nature are 'chart reviews' and subject to recall bias i.e. reliant on accuracy of written records and recall of individuals. Also because of lack of randomization and lack of blinding, retrospective reviews are subject to confounders.

We feel that the parachute example in defence of not agreeing to a RCT cited by Donnez *et al.*¹ was inappropriate. Although there is no present alternative to a parachute, hysterectomies can be performed by modalities other than laparoscopic. To increase the validity of Donnez *et al.*¹ hypothesis of the safety of the laparoscopic approach, we urge a robust multicentre/multinational RCT. For precise comparison of the groups, it is essential that optimum operator experience and complications are predefined. Hopefully, following the RCT, we wouldn't have to warn our patients about a higher risk of urinary tract injury and of severe bleeding associated with laparoscopic hysterectomy as compared with open surgery.⁴ ■

References

- 1 Donnez O, Jadoul P, Squifflet J, Donnez J. A series of 3190 laparoscopic hysterectomies for benign disease from 1990 to 2006: evaluation

of complications compared with vaginal and abdominal procedures. *BJOG* 2009;116:492–500.

- 2 Gary R. Best way to determine the best way to undertake a hysterectomy. *BJOG* 2009;116:473–6.
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Author's Reply

Sir,

We do not agree with the remarks of Gandhi and Saha¹ and would like to set the record straight.

Indeed, in stating that 'all of these studies are retrospective and by their nature are «chart reviews» and subject to recall bias', Gandhi and Saha are clearly unaware that, in Belgium, a registry of complications was initiated in 1990 to record the complication rate in the three main institutions where laparoscopic hysterectomy was first developed.

In 1995, during the ESGE Congress in Brussels, the complication rate of laparoscopic hysterectomy issued by the registry was reported and discussed. A comparison was made with vaginal and abdominal hysterectomy, but failed to detect any significant difference. At St Luc's University Hospital, we decided to continue reporting all complications prospectively.

Our study is therefore not a retrospective study subject to recall bias, as Gandhi and Saha claim. It is an analysis of all complications, carefully and *prospectively* reported, reanalysed from written accounts and recorded videos.

We dispute the need for a robust multicentre, multinational RCT 'to increase the validity of Donnez *et al.*'s hypothesis of the safety of the laparoscopic approach'. Gandhi and Saha are clearly referring to the NICE Guidelines paper published in 2007 (cited in 1).

Once again, this paper, in which the higher risk of urinary tract injury and severe bleeding with laparoscopy compared to open surgery was obviously due to the relatively limited experience of some of the laparoscopic surgeons involved, is being cited as some kind of standard.

Once again, papers by Bojahr *et al.*, Karaman *et al.* and Wattiez *et al.* (cited in our manuscript)² are simply being disregarded.

Moreover, Gandhi and Saha fail to mention the Finnish study, which included 56 130 hysterectomies,³ with a ureteral complication rate of just 0.3% after laparoscopic hysterectomy.

Are Gandhi and Saha trying to cast doubt on all these studies, including the very formidable Finnish series? It is time they accepted that the higher complication rate in the eVALuate study was because of the learning curve.

We maintain that the parachute remains a good example.⁴ Indeed, a bad surgeon is like a bad parachute and the complication rate will be higher in both instances!

Gynecologists were the pioneers of laparoscopic surgery after all, long before general surgeons got in on the act. Frangenheim, Palmer, Semm, Bruhat, to name but a few, laid the ground and opened the doors to a laparoscopic approach. General surgeons only caught up some time later.

I strongly suggest that Gandhi and Saha take a close look at some of the more recent publications, books and videos by general surgeons. They will see that these surgeons are now ready to take over all manner of surgical procedures of the peritoneal cavity, without any hesitation whatsoever.

If gynaecologists like Gandhi and Saha continue to advocate open surgery instead of laparoscopic surgery for cases that can easily be managed by laparoscopy, we should not be surprised to see general surgeons routinely performing hysterectomies in the future!

To cite a case in point, twenty years ago, uterine prolapse surgery was carried out exclusively by gynaecologists by the vaginal route. Now, it is laparoscopically performed by surgeons, urologists and gynecologists alike.

We should know what we want—and improve our skills accordingly—before we get left behind! ■

References

- 1 Gandhi P, Saha A. Have the safety concerns about laparoscopic hysterectomy been fully addressed? *BJOG* 2009;116:1272.
- 2 Donnez O, Jadoul P, Squifflet J, Donnez J. A series of 3190 laparoscopic hysterectomies for benign disease from 1990 to 2006: evaluation of complications compared with vaginal and abdominal procedures. *BJOG* 2008;116:492–500.
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Author's Reply

Sir,

I thank Drs Gandhi and Saha¹ for their observations. I believe all are agreed that surgical interventions should be subjected to rigorous assessment. The controversial issue is which methods of assessment are most appropriate?

In their rebuttal² to my commentary,³ Donnez *et al.* quoted the humorous Christmas issue paper suggesting that the use of a parachute gave results that did not require a RCT to determine its efficacy.⁴ This is of course true, but is it also true for assessing the best method for hysterectomy? When a single obvious parameter (death) is the outcome and a single modality (using a parachute) is investigated, then a simple retrospective analysis is appropriate. This approach is usually insufficient, however, if two interventions are compared. The differences observed when comparing round and oblong design of parachute will be much less as most people using both types will avoid death. A more sensitive analysis is then required. The difficulty in analysis will be further increased if round parachutes are army issue, used only by fit, disciplined and well-trained soldiers and the oblong parachutes are the toys of the adventurous but untrained who need a few beers to make the jump. The confounding factors of training, fitness and beer may influence the outcome more than the type of parachute used. To overcome the effect of these confounders, trained and untrained, fit and unfit, alcohol and no alcohol, parachutists must be equally distributed between the two parachute designs. This is achieved by randomisation.