Why we need international agreement on terms and definitions to assess clinical outcome after endometriosis surgery

Sir,

We congratulate the authors of a prospective clinical outcome study after conservative surgery by the shaving technique for deep rectovaginal endometriotic (RVE) nodules (Donnez and Squifflet, 2010). We do however have some post-publication peer review comments (Anderson, 1999).

Firstly, onl y one group worldwide has published outcome data after the shaving technique in two studies in the last 16 years (Donnez et al., 1995; Donnez and Squifflet, 2010). Other groups have reported clinical outcome after conservative surgery for deep RVE nodules, but always in cohorts mixed with patients treated with bowel resection anastomosis (mixed study groups, n = 16: Meuleman et al., 2011a), except for one paper describing outcome after discoid excision only (Nezhat et al., 1994). In contrast, twice as many papers (n = 32) have documented the outcome of bowel resection anastomosis (Meuleman et al., 2011a) and overall, the endometriosis recurrence rate was lower in the bowel resection anastomosis group (5.8%) than in the mixed study group (17.6%) (Meuleman et al., 2011a).

Secondly, the study (Donnez and Squifflet, 2010) included selected ‘good prognosis patients’ without previous surgery for endometriosis, including cases with non-adherent type II lesions (easy to dissect) and excluding cases with bowel endometriosis in other or in multiple parts of the bowel system (rectosigmoid, sigmoid, small bowel, etc.) and any conclusions made need to take this into account. It is unclear how many cases with rectosigmoid endometriosis were diagnosed on a pre-operatively, and how these cases were handled surgically.

Thirdly, in this prospective study (Donnez and Squifflet, 2010), a number of key variables were either not reported, not standardized or not defined: no exact start and end dates of patient recruitment, no correction for the duration of follow-up per patient (no life table analysis), no documentation of follow-up (method, type of assessment during follow-up, number lost for follow-up, etc.). Outcome assessment of pain or quality of life was not patient based although validated and recommended methods exist (Vincent et al., 2010), have been applied (Meuleman et al., 2009; Meuleman et al., 2011b, submitted for publication), are recommended (Harvey and Warwick, 2010) and moreover underlined by the President of the World Endometriosis Foundation (Evers, 2010), and are essential to document possibly compromised sexual function after removal of the posterior vaginal fornix (Donnez et al., 2010). Complications or recurrences were not defined, even though recurrence of severe pelvic pain was high (20%) among non-conceiving patients in this good prognosis population (Donnez and Squifflet, 2010).

Fourthly, Table III (Donnez and Squifflet, 2010) includes only 11 selected papers, whereas 32 papers have documented clinical outcome after bowel resection anastomosis resulting in a visually and/or histologically proven recurrence rate of 2.5% only (Meuleman et al., 2011a).

Fifthly, our work (Meuleman et al., 2009) is not correctly discussed. We studied (Meuleman et al., 2009) clinical outcome in a highly selected (<3% of all laparoscopies between 1996 and 2004) group of patients with mostly (75%) recurrent deeply infiltrative endometriosis with colorectal extension requiring radical nodulectomy and multidisciplinary surgery. The more severe clinical picture of our study population (Meuleman et al., 2009) compared with the ‘good prognosis’ patients included in this study (Donnez and Squifflet, 2010) partially explains the longer duration of surgery. The duration of our surgery (Meuleman et al., 2009) was not exceptionally long, as five other studies reported a mean/median duration of surgery of at least 300 min (Lyons et al., 2006; Darai et al., 2007; Minelli et al., 2009; Pereira et al., 2009; Ruffo et al., 2010).

Additionally, long duration of surgery has to be balanced against our low rate of complications, reinterventions and recurrences and high rate of pain relief, improvement of quality of life and fertility (Meuleman et al., 2009) confirmed prospectively (Meuleman et al., 2011b, submitted for publication), according to terms and definitions proposed recently in a CONSORT-based checklist (Meuleman et al., 2011a). Although the incidence of lower leg compartment syndrome was indeed 5% (3/56) in our series (Meuleman et al., 2009), subsequent measures have been successful to prevent this complication subsequently (Tomassetti et al., 2009). Furthermore, nerve sparing surgery is possible during colorectal segmental resection (Meuleman et al., 2009). Finally, the decision to do a bowel resection anastomosis does not need to be justified by the presence of mucosal infiltration in the resected specimens, but was based on limited integrity of the bowel wall after radical nodulectomy, not restorable by bowel suture, primarily in order to prevent post-operative bowel complications (Meuleman et al., 2009), and the same approach is advocated by other groups (Keckstein and Wiesinger, 2005; Serachioli et al., 2007; Dousset et al., 2010).

References

Letters to the Editor

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Reply: Why we need international agreement on terms and definitions to assess clinical outcome after endometriosis surgery

Sir,

We appreciate the letter by Meuleman et al. and thank them for their comments. Indeed, it is always good to initiate this type of debate, which may continue for many years to come. We will do our best to answer point by point:

(i) Our study (Donnez and Squifflet, 2010) is not the second but the fourth by our group and, right from the outset, we have stressed that, all too often, an overly radical approach is proposed in case of deep endometriotic lesions with rectal muscularis involvement. We disagree that we are the only group advocating the shaving technique. Increasingly a number of groups (Landi et al., 2006; Slack et al., 2007; De Cicco et al., 2009; Roman et al., 2010, 2011; Koooro et al., 2011) are recommending this technique and acknowledging that bowel resection (performed in their previously published series) was probably not necessary in the majority of cases.

In their letter, Meuleman et al. state that 32 papers have documented the outcome of bowel resection, suggesting that this is sufficient proof of the merits of this technique. We respectfully beg to differ. The letter also suggests that our data have not been confirmed by other groups. We would however like to draw attention to the following publications: (Landi et al., 2006; Slack et al., 2007; De Cicco et al., 2009; Roman et al., 2010), and reiterate that the shaving technique is being increasingly used because of the high risk of complications after bowel resection.

(ii) If the description of our study population was unclear, we apologize. For clarity, 204 patients (40.8%) had type III lesions, defined per se as infiltration of the rectal muscularis (Squifflet et al., 2002). Moreover, >50% of type II lesions also showed rectal muscularis involvement. Thus, in our series of 500 cases, over 70% of patients presented with rectal muscularis involvement. All the cases in our series were diagnosed by barium enema, providing a very accurate analysis.

We agree that to reach any legitimate conclusions, only pure cases should be considered. However, all series (n = 32) published so far have included mixed pathologies, unfortunately resulting in a patchwork of conclusions.

(iii) We certainly agree that quality of life is important and should be analyzed, but the majority of questionnaires fail to evaluate the detrimental and psychologically damaging effects of large median laparotomy with ileostomy or colostomy (even if temporary) in young women. Importantly, such questionnaires should assess the sex life of these young patients after extensive surgery and maybe ask the partner’s opinion. In short, there are numerous factors to consider when analyzing quality of life post-surgery.

Regarding removal of the vaginal fornix, in 2000, at the World Endometriosis Society congress in London, we presented the results of a comparative study demonstrating the need for removal of the posterior vaginal fornix (Donnez et al., 2001). Indeed, we showed that (i) the recurrence rate of dysmenorrhea and deep dyspareunia was higher if the vaginal fornix was not removed and (ii) the vaginal fornix usually contained endometrial glands and stroma sometimes arising from the vaginal mucosa itself. This was further evidenced by one of our histological studies (Donnez and Squifflet, 2004), and has since been confirmed by Matsuzaki et al. (2009) and Roman et al. (2010).

Leaving the vaginal fornix in place exposes the patient to a higher risk of recurrence of deep dyspareunia (Donnez and Squifflet, 2004). Not surprisingly, in other departments where gynecologists...