Letters to the Editor

Sir,

Detry-Morel et al. are to be complimented for designing a study attempting to answer the question of the efficiency and safety profile of ''modern'' trabeculectomy compared to non-penetrating deep sclerectomy (NPDS) (1). Modern trabeculectomy (mTRAB) was done according to Khaw ́s protocol. A reticulated hyaluronic acid implant (SKGEL) was used in deep sclerectomy eyes. Their retrospective results suggest that mTRAB leads to a higher success rate accompanied by a more favorable safety profile than NPDS. An IOP < 16 mmHg was achieved in 70% of trabeculectomy cases and in only 41% NPDS eyes ($p < 0.05$).

We would like to highlight the fact that this comparative non-randomised retrospective study suffers from a number of significant limitations that have probably influenced the study findings. The non-randomised retrospective approach is a choice that has its obvious weaknesses. And it is for a good reason that most modern studies looking at different therapeutic interventions chose the randomized controlled trial format. A non-randomised retrospective study cannot prevent selection bias. And this paper is a case in point.

There are important differences in patient demography between the two groups. On average, NPDS patients are almost 10 years older ($P<0.05$). Furthermore, there are more pseudophakes ($p<0.05$) in the NPDS group. These are not mere statistical by-products, on the contrary, it has been shown amply that these are all relevant negative prognostic factors for surgical outcome (2,3,4). Patients also had a significantly lower preoperative visual acuity in the NPDS (0.6 versus 0.8).

Other differences that, although not significant, point to a general tendency towards more severe glaucoma in the non-penetrating group are the longer duration of medication use (132 versus 115 months), the higher rate of patients with more severe visual field defects, as well as the use of intraoperative antimetabolites which was higher in the NPDS group (77% versus 58%). Antimetabolites can be a potential source of severe postoperative complications such as non-filtering or leaking blebs (5,6).

We do not know whether the small and imbalanced sample size of 22 NPDS and 43 mTRAB eyes (55 patients in total) warrants sufficient statistical power to detect relevant differences between the two groups. Unfortunately, the authors do not provide information on this point.

It is of interest to note that NPDS patients have a significantly longer follow-up period than their mTRAB counterparts (10.7 versus 8.5 months). It has been shown that late postoperative complications occur between the 4th and 18th postoperative month. Hence, it is natural to find more complications with a longer follow-up period.

In their paper, Detry-Morel et al. rightfully point to some of the limitations of the study and we believe that because of these the groups were not well matched. Nevertheless, they conclude that ''modern trabeculectomy was associated with a safety profile similar'' to deep sclerectomy and that ''mTRAB was associated with slightly, although not statistically significant, higher IOP reduction than NPDS''. As was stated, their assertions are not based on a direct comparison but on a single retrospective case series. We believe that due to the substantial differences between the groups studied, these conclusions should not be taken at face-value and should not be extrapolated to any other group than the one studied here. This point is validated by numerous other published reports with superior study designs that contradict this paper's outcomes (8,9,10,11).

Once again, we would like to acknowledge the efforts put into this study and look forward to more randomised controlled trials, especially addressing the position of NPDS in the armamentarium of glaucoma therapies.

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Reply

Dear Editor,

We appreciate Drs Mansouri's and Shaarawy's interest in our article and thank them for their pertinent and extensive comments.
As developed in the discussion, we were fully aware of the significant limitations and bias of this study. The readers were advised to critically interpret the presented data. We stated that this study was retrospective non-randomized and involved two different small size groups which were well-matched in terms of risk for surgical failure but not in terms of sample size, age, mean follow-up and number of pseudophakic eyes. We reflected this concern in the content of the manuscript and drew our conclusions very cautiously, especially in terms of comparative IOP reduction and success rates between the two techniques, all the more the follow-up and the sample size groups were too short to draw reliable conclusions.
After a 5-year personal experience including more than 135 deep sclerectomies, we have progressively shifted our filtering surgical procedures from deep sclerectomy (NPDS) to "modern" trabeculectomy (MTRAB) (1). We aimed at evaluating whether this revisited P. Khaw's technique of trabeculectomy could allow us both

to increase our surgical success and to reach a safety profile comparable to those of deep sclerectomy, especially in the peroperative and the early postoperative period.
The primary, even more the sole purpose of our study was ''to compare the incidence and the severity of the peroperative, the short-term complications (i.e occurring in the 1st postoperative month) and the medium-term complications (i.e that developed during the 3 to 6 postoperative months) following ''modern'' trabeculectomy with those that occurred after non-penetrating deep sclerectomy''. We found that the incidence of peroperative complications was low and very similar in the two groups. Importantly, the incidence of the 1st month postoperative complications, especially the potentially vision-threatening complications associated with shallow anterior chamber secondary to hyperfiltration, was not significantly different between the two procedures. Most of the medium-term complications were minor and transient in both groups. In our study, the MTRAB group included significantly more numerous phakic eyes than the NPDS group. Since the frequency of anterior chamber shallowing is most often higher in phakic than in pseudophakic eyes in one hand and after standard trabeculectomy than after non-perforating filtering procedures in the other hand, the fact that the incidence of this complication was comparable between our two groups would argue in favour of the potentially good early safety profile of MTRAB. Unlike Drs Mansouri and Shaarawy have objected, the frequency of intraoperative antimetabolite application was not statistically different between the two groups, while mitomycin C had been used at lower doses than usually recommended. Furthermore, peroperative antimetabolite augmentation did not seem to influence the frequency of distribution of complications in both groups. In our discussion, we also reminded the reader of ''the potential long-term complications associated with intraoperative use of Mitomycin that should warn of the potential dangers of routinely using antimetabolites during surgery''.
Except for three cases of iris incarcerations following Nd:Yag goniopuntures in eyes with open-angle glaucoma in the NPDS group, we did not observe any sight-threatening complication between the 1st and the 6th postoperative month with both techniques.
The mean preoperative visual acuity was actually significantly higher in the MTRAB than in the NPDS group. However the fact that the visual recovery was similar in each surgical procedure at the last visit was important to be stressed on.
Finally, the fact that the NPDS group tended to include more severe glaucoma did not appear to influence the incidence of postoperative complications.
Based on these findings, we confirm that we could conclude that ''revisited trabeculectomy was associated with a safety profile (especially concerning hyperfiltration related complications) similar (and even more, slightly higher than) to those of non-penetrating drainage glaucoma surgery, whether procedures have been augmented with intraoperative antimetabolite or not''. However and based on our limited experience and heterogeneous sample size, we indeed could not conclude that MTRAB had definitely a better safety profile than NPDS.
Again, we thank Drs Mansouri and Shaarawy to have given us the opportunity to share our ideas and to have stressed on the huge and urgent need of conducting more prospective randomized controlled clinical trials in this fascinating and ever moving field that is glaucoma surgery.

Bull Soc belge Ophtalmol 2006, 300:43-54.

RÉFÉRENCE

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