

## Treatment of chronic fistula-in-ano using commercial fibrin glue

To the Editor

Regarding the prospective study on using commercial fibrin glue in the treatment of chronic fistula-in-ano,<sup>1</sup> I have a few comments, some of which are specific to this study and others are related to other prospective studies on human subjects that were published in the Journal.

1. The inclusion criteria in the above paper at the outset of the study were vague, they included patients with "low fistula-in-ano". However, low fistula can be simple or complex<sup>2</sup> and the authors did not mention these details. Moreover, there was no mention of any underlying disease such as inflammatory bowel disease, tuberculosis or human immunodeficiency virus. These details are important especially when 68% of their patients were treated for recurrent fistulae and 10% had more than one fistula. The type of fistula and the underlying disease have been shown to affect the success of treatment by fibrin glue.<sup>2-4</sup>

2. In the discussion, the authors cited other studies that compare favorably with their study, however, there are other studies that showed 100% failure rate<sup>5</sup> or no advantage of fibrin glue over conventional fistulotomy for low, simple fistula in a prospective randomized trial.<sup>2</sup> Moreover, 15.7% of the authors' patients (3 patients) were lost to follow-up. If these patients healed successfully, the rate would have been 81% but if they did not heal, were unhappy and moved to another institution for treatment, the healing rate would have dropped to 66.6%.

3. I agree with the authors that long-term follow-up is needed to determine the long-term results. The literature on this issue is encouraging; however, recurrence up to one year later were being seen.<sup>6,7</sup> Although fibrin glue may appear attractive, the studies do not address whether this technique ever resulted in the resolution of sepsis or simply temporary symptomatic relief, while tracts remain blocked.<sup>3</sup> Moreover, the diagnosis of recurrence can be underestimated by subjective symptoms or even examination under anesthesia and magnetic resonance imaging which has been shown to be a better predictor of fistula healing.<sup>3,8</sup> The fact that this treatment is "safe, simple and easy for the surgeon to perform" as stated repeatedly by other authors<sup>9,10</sup> and almost verbatim in the present paper,<sup>1</sup> does not automatically warrant ignoring the need to follow evidence-based practice and put this method under the rigorous scrutiny of the gold standard prospective randomized trials.

4. In this prospective trail, the authors did not mention if the study was approved by an institutional review board or if patients' informed consent was obtained. Another example of the importance of publishing these statements is an experimental new method depicted in a case report published 2 years ago by the journal.<sup>11</sup> The Saudi Medical Journal follows the uniform requirements for manuscript submitted to biomedical journals,<sup>12</sup> and the ethical standards of the Helsinki declaration when publishing studies on human subjects.<sup>13</sup> Thus, I am confident that the editorial board insures that statements by the authors regarding such issues are always received. However, it is prudent in my opinion, to include these statements in the published papers. This will strengthen the credibility and reliability of the journal and alert trainees, young practitioners and indeed all readers to these important ethical issues. Enthusiasm to embark on new methods of treatments, should not dampen our concerns to our patients' well being, rights and the proper scientific and ethical principles.

Finally, I congratulate the authors on their work and look forward to see larger series and longer follow-up to establish this simpler and safer treatment in a prospective randomized controlled trail.

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### Reply from the Author

Author declined to reply.

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