FIBRINE GLUE INJECTION FOR PERIANAL FISTULAS IN CROHN'S DISEASE: A RANDOMIZED CONTROLLED TRIAL

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INTRODUCTION: Fibrin glue (FG) is a new option in anal fistulas. This simple technique can be used and repeated without jeopardizing anal continence. Data concerning its effectiveness in Crohn's disease (CD) are scarce. The aim of this multicentre randomized controlled trial was to assess efficacy and safety of a FG (a combination of fibrinogen, factor XIII, plasminogen, thrombin and bovine aprotinin) injected in the fistula tracts of CD patients.

AIMS & METHODS: Methods. CD pts with fistula between anus (or low rectum) and perineum, vulva or vagina, draining for >2 mo were eligible. CDAI had to be <250 at baseline. MRI or endosonography was performed to assess fistula tracts and ensure that there was no abscess. Concurrent therapies with stable doses of immunosuppressants (>3mo), 5-ASA, or steroids <15mg/d were permitted, but not anti-TNFs (last infusion >3mo) and cyclosporine. Setons were removed at entry. Stratum 1 included pts with simple fistula; stratum 2, those with more complex fistula (multiple tracts or ano/rectovaginal fistula). In each stratum and center, pts were randomly assigned to FG injections in the fistula tracts or no treatment (NT). The primary endpoint was complete response at week 8 (W8), defined as the absence of perianal pain and of draining fistulas. At W8, pts with no/partial response were offered the possibility to be treated (NT group) or re-treated (FG group) with FG. All pts were re-evaluated at W16.

RESULTS: Results. At 12 centers participating to the trial, 77 pts (51F, median age: 35yrs) were enrolled, 36 in the FG group and 41 in the NT group. Median CD duration was 6.7 yrs, and fistulas were present since 1.8 yrs. 41 pts (53%) had a simple fistula (stratum 1). Prior treatments were antibiotics (84%), immunosuppressants (78%), infliximab (44%) and perianal surgery (91%). At W8, 13/34 (38%) of assessable pts had a complete response in the FG group, compared to 6/37 (16%) in the NT group ($p<0.05$); in stratum 1, complete response rates were 50% vs 22% respectively; in stratum 2, 25% and 11% (no interaction treatment x stratum). In FG responders at week 8, 83% maintained response at W16. FG was injected at W8 in 19 patients of the NT group and 10 (53%) had a complete remission at W16; in the 6 patients of the FG group who were re-treated at W8, none had a complete response at W16. Adverse events, mostly mild or moderate, occurred in 11% FG) and 15% (NT) of pts, including 1 and 3 perianal abscesses, respectively.

CONCLUSION: Conclusion. Fibrin glue injection is effective for achieving complete closure of anal fistulas in patients with inactive CD. The procedure appears safe, and should be regarded as a good option in patients with persisting or relapsing perineal fistulas without intestinal symptoms.