A randomised trial of fibrin glue vs surgery for pilonidal sinus disease: Results and long term follow up.

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Abstract:

Purpose: There is no consensus on the optimal treatment for pilonidal sinus disease. Treatment with fibrin glue is a novel minimally-invasive technique which we compared to conventional surgery. Methods: Forty consecutive patients with pilonidal disease were randomized to either fibrin glue treatment (FGT) or Bascom's procedure. 20 patients per group were required for a 90% chance of detecting a 10% difference in pain at the 5% level. Patients completed a validated Quality of Life questionnaire (QoL) daily for the first week and were followed up at six weeks. End points included infection rates, healing, QoL scores, analgesic requirements and convalescence time. Long-term recurrence in each group was also assessed. Results: Pain scores (worst pain = 10) were reduced at 2.5 vs 5 on day 1 in the FGT group compared to the Bascom's group, and 1 vs 4.47 on day 7 ($P < 0.05$). Analgesic use scores at day 1 and day 7 were 2.5/10 and 1/10 in the FGT and 5/10 and 4.47/10 in the Bascom's group ($P < 0.05$). Normal mobility was achieved by 19/20 of FGT patients by day 7 vs 5/19 of those randomised to surgery. This remained statistically significant at week 6. Patients in FGT group returned to work on average 7.2 days post-operatively compared to 42 days in the Bascom's group. There was a significantly superior QoL score in the fibrin glue group (39.9 vs 31.9, $P < 0.05$) both at day 7 and sustained through week 6. There was no statistically significant difference in wound infection rates (FGT:3, 15% vs Bascom's group: 5, 25%, $P > 0.05$). Median follow-up was 4.63 (range 3.87-6.09) years with two (10%) recurrences in the Bascom's group and 3 (15%) in the FGT. Recurrences were treated successfully with further surgery. An estimated direct cost reduction of 2205 per patient was achieved by reduced post-operative wound care

requirements in the fibrin glue group. Conclusion: The use of fibrin glue is an effective treatment for pilonidal disease, with improved patient centred outcomes. The long-term recurrence rate was no different from surgery in this small group. Fibrin glue should be considered as an alternative to conventional surgical techniques in suitable cases, having potential benefits in terms of reduction of post-operative morbidity and overall cost.