A randomized prospective double blind controlled trial on effects of fibrin sealant in cementless hip replacement.

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Abstract:

Total hip replacement (THR) surgery can expose patients to significant perioperative blood losses. This prospective, controlled, randomized, double blind study evaluated the efficacy in reducing postoperative bleeding and blood transfusion using a commercially available human fibrin sealant in primary cementless THR. Sixty-eight patients, who were planned to undergo THR and who met the inclusion criteria, were randomised in a 1:1 ratio into two groups: a treatment group, in which fibrin sealant was used after prosthesis implantation and a control group using saline. Twenty patients had provided autologous blood through self-transfusion and forty-eight patients had not. Patient randomization did not consider predeposit of autologous blood. Each group followed the same haemostatic procedures, anaesthesiological protocol and venous thromboembolic prophylaxis. Intra- and post-operative blood loss was evaluated through standardized protocols. Haemoglobin (Hb) and haematocrit (Ht) levels were registered preoperatively and on post-operative day 1, 2, 3 and 7. The number of transfused blood bags was recorded. Six patients (17 percent) of the control group required homologous transfusions and one patient (3 percent) of the treatment group required homologous transfusions ($p<0.05$). The mean number of transfused homologous blood units in the control group was 0.34 compared with 0.05 in the treatment group ($p<0.05$). Comparing for the whole autologous and homologous transfusions, a selected control group, who had done blood deposit through self-transfusion, received a mean of 1.22 autologous bags, while a selected treatment group who had not done any self-blood predeposit before surgery received a mean of 0.08 homologous bags with a mean difference of 1.14 ($p<0.001$). Considering only patients who did

not undergo autologous blood predeposit, average Hb concentration in second and seventh day after surgery was respectively 10.28 and 10.26 g/dl in treatment group compared with 9.68 and 9.61 g/dl in control group, with a mean difference of 0.60 and 0.65 g/dl ($p<0.05$). Surgical use of human fibrin sealant reduced the requirement of homologous blood transfusions after primary standard cementless THR, and maintained higher post-operative Hb levels. Moreover routine use of this off the shelf topic fibrinogen-based haemostatic could, in the future, possibly be used as an alternative to autologous blood pre-deposit.