

**Microporous Polysaccharide Hemospheres, A Plant Based Topical Hemostatic Agent,
For Bleeding Control Of The Sternum**

Helmut Mair¹, Mark Ereth², Albert Schuetz³, Sabine Daebritz³

¹Cardiac Surgery, University of Leuven, Leuven, Belgium,

²Mayo Clinic Rochester, MN, USA and

³Cardiac Surgery, University of Munich, Munich, Germany

Introduction:

Profuse bleeding after sternotomy is routinely controlled with bone-wax (BW). Unfortunately, bone-wax may cause non-union of the sternum and infections. Microporous Polysaccharide Hemospheres (MPH), a resorbable plant based hemostatic agent, offers a novel technique to control sternal bleeding during cardiac operations. This study evaluates the efficacy and safety of MPH as a topical hemostatic first time in human use.

Methods:

Eighty patients with beating heart revascularisation were included in this prospective randomized trial. In 40 patients (pts; group-MPH) the MPH (AristaAHTM, Medafor Inc., Minneapolis, MN) was applied directly after sternotomy. The other 40 pts (group-BW) were treated with standard use of BW. The two groups did not differ in demographic and intraoperative data (age: 68.5±6.4 vs. 67.6±7.6years; grafts: 2.9±0.6 vs. 3.2±0.8). All patients were operated with an activated-clotting-time of >350 sec and Protamine was given after revascularisation was completed.

Results:

Satisfactory bleeding control of the sternum was achieved in 37 pts (93%) with MPH and in 39 pts (98%) with BW. Application of BW was rated easier, but destruction of sternal spongiosa in osteoporotic bone was more common using BW ($p < 0.05$). The intraoperative decrease of Hemoglobin (Hb) was not significant (n.s.) between the groups (MPH: Hb preop 13.0±1.3mg/dl to Hb postop 10.5±1.5mg/dl vs. BW: Hb preop 12.9±1.6mg/dl to Hb postop 9.9±1.6mg/dl). Autologous transfusion (cell-saver) (MPH: 194±150ml vs. BW: 268±245ml), allogenic blood-units (MPH: 2 pts vs. BW: 3 pts) and postoperative blood loss (MPH: 880±460ml vs. BW: 830±520ml) did not differ significantly. We observed no allergic reaction, no reoperation due to graft failure and no death in either group. There was one resternotomy due to sternal instability in each group. Only in group-BW two wound-healing problems occurred (n.s.).

Conclusion:

MPH can be applied safely and effectively and can replace bone wax.