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Title **Autologous Fibrin Sealant – Vivostat® System**

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Reference Technology Review Report, 005/07, 2007.
http://medicaldev.moh.gov.my/uploads/vivostat.pdf

Aim

To assess the safety, effectiveness, cost effectiveness, and ethical implications of the Vivostat® System as an autologous fibrin sealant.

Conclusions and results

Based on the 5 randomized clinical trials (RCT) published (4 trials related to hemostasis and 1 trial related to air-leak prevention) the Vivostat® system appears to be capable of producing relatively safe and effective autologous fibrin sealant preoperatively. However, 2 of the 5 RCTs reviewed lacked a suitable comparator. One must be cautious in interpreting the above findings as only one of the studies published was conducted by an independent researcher.

Recommendation

Vivostat® system may have a role to play as an autologous fibrin sealant in planned preoperative surgery.

Methods

Literature was searched via MEDLINE (July 1966-week 3, 2007), Current Contents (1993-week 27, 2002), and Cochrane Controlled Trials Register (Cochrane Library, Issue 2, 2002). These databases were initially searched using the search terms: 'vivostat'; 'autologous fibrin sealant'; 'autologous fibrin glue'; 'patient derived sealant'. Relevant publications were examined for references until no further studies were found.

Total number of studies: 9

1. Horizon scanning: 1 from Horizon Scanning Australian Safety And Efficacy Register of New Interventional Procedures - Surgical (ASERNIP-S). This systematic review looked at 4 RCTs, namely Belboul et al (2004), Drake and Wong (2003), Hanks et al (2003), Kjaergard and Trumbull (2000)
2. Another RCT: 1 study by Kjaergard and Trumbull (1998)
3. Case series studies: 4

Systematic reviews and RCTs were reviewed as this yield the highest quality of evidence required to examine issues of safety and effectiveness. Case studies were excluded.

Autologous Platelet Rich Fibrin (PRF®) was excluded from this technology review.

The evidence was synthesized using the qualitative approach to draw conclusions.

Further research/reviews required

More randomized trials need to compare existing hemostatic agents with the Vivostat® system to determine the effectiveness of this autologous system.

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