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Title Benefit of the autologous fibrin sealant Vivostat®

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Reference Evaluations de technologies de santé
Vivostat® - colle de fibrine autologue

Aim

To update a previous report from 2006, which found data insufficient to recommend the product in clinical routine practice and to reassess the autologous fibrin sealant Vivostat® produced by Vivostat A/S.

Conclusions and results

Technical aspects: surgical haemostatic agents have either a human origin (fibrin sealants), or a synthetic, animal or vegetal one, and have the legal status of drugs (medicines)or medical devices. Vivostat® is a medical device made on autologous human fibrin (extracted from the own blood of the patient). Its preparation takes 23 minutes before the surgical intervention and 120 ml of the patient's blood, and leads to a 4 to 6 ml fibrin sealant product. According to the 2006 assessment report of CEDIT, Vivostat® could have a better immediate adhesion and in vitro elasticity than other fibrin sealants. Moreover, at the time, the application system of Vivostat® blocked less frequently than other systems and the precision of use seemed better.

Clinical aspects: few clinical studies and data were published since the 2006 report of CEDIT and the 2011 report on surgical hemostatic agents released by the French National Authority of Health (HAS). The clinical studies available with fibrin sealants show that their use provides a modest benefit in terms of aerostasis and hemostasis (blood loss reduced on average by 160 ml per intervention according to a Cochrane revue). For Vivostat®, the absolute benefit will thus be around 40 ml. No clinical study currently shows a better efficacy or safety compared with other fibrin sealants. The autologous nature of this product is used to emphasize its safety (less infectious and immunological side effects), but no scientific data supports this assumption. Besides, for this product whose preparation has to be anticipated, the necessity to select before the surgical intervention the patients most likely to benefit (on criteria not yet standardized) will influence the effectiveness of this product.

Economic aspects: according to the available data, the equipment needed for the preparation of Vivostat® would call up around 40,000 euros (24,000 in the 2006 CEDIT's report). Moreover, each single use kit would cost between 400 and 500 euros (360 at 440 in the 2006 report). The price of the other fibrin sealants with the status of drugs (medicines) is negotiated among firms and hospitals. No economic evaluation study on Vivostat® was found. Given the current clinical data available, a superior cost of Vivostat® would be a sign of an unfavorable cost-effectiveness ratio in regard with other fibrin sealants. Moreover, the necessity to anticipate its preparation for a use that is then not certain would diminish the cost-effectiveness ratio in real clinical practice.

Organizational aspects: the use of Vivostat® in the operating room involves the presence and the maintenance of different devices and machines directly or indirectly (sterilization) needed, a more complex process than the storage and the use of other fibrin sealants which are virtually ready to be used.

Recommendations

Few data are available on Vivostat® compared with that published for other fibrin sealants. Moreover, no clinical study directly compared Vivostat® to these products. Vivostat® is thus a medical device whose clinical, economic and organizational benefits are not currently proved.

Methods

A product specific search of peer reviewed literature up till September 2014 was undertaken for Vivostat® autologous fibrin sealant. No general review of sealants and hemostatic products was made. A working group of potential users (surgeons) was organized. No direct contact with the manufacturer was established for the purpose of the review.

Further research/reviews required

Nevertheless, this product being considered as potentially interesting by surgeons, CEDIT considers that the use of Vivosta® should be made possible at AP-HP, providing that it is carried out into a randomized comparative clinical study, or at least into a cohort study compared with historical or contemporary references.

Written by

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