Scottish Medicines Consortium

TachoSil® medicated sponge No. (344/07)

Nycomed

12 January 2007

The Scottish Medicines Consortium has completed its assessment of the above product and advises the NHS Boards and Area Drug and Therapeutic Committees on its use in NHS Scotland. The advice is summarised as follows:

ADVICE: following a full submission

TachoSil® medicated sponge is accepted for use within NHS Scotland for supportive treatment in surgery for improvement of haemostasis where standard techniques are insufficient.

In addition to the previous SMC advice for Tachosil use in liver surgery the economic case for renal surgery has also now been demonstrated.

Overleaf is the detailed advice on this product.

Chairman
Scottish Medicines Consortium

Indication

For supportive treatment in surgery for improvement of haemostasis where standard techniques are insufficient.

Dosing information

The number of sponges applied is governed by the size of the wound area. Application must be individualised by the treating surgeon. In clinical trials the individual doses have typically ranged from 1-3 sponges (9.5cm x 4.8cm).

Product availability date

March 2006

Summary of evidence on comparative efficacy

Supportive treatments such as fleeces and sealants are used to control wound bleeding during resection surgery. TachoSil® consists of a collagen sponge coated with human fibrinogen and thrombin. On contact with physiological fluids, the coagulation factors dissolve, initiating the last phase of physiological blood coagulation. The formation of a fibrin clot brings about haemostasis, making the collagen adhere tightly to the wound and providing wound sealing.

There has been one phase lll, open, randomised study evaluating the haemostatic efficacy and safety of TachoSil® in 185 patients undergoing planned, open resection of a superficial renal tumour which had not infiltrated the urinary tract and did not require major kidney resection or extirpation. After kidney resection, primary haemostasis of major vessels was performed as usual and once this was achieved and when the resection wound was suitable, patients were randomised to TachoSil® (n=92) or standard treatment (suturing) (n=93). The primary outcome was the time to haemostasis in minutes in the intention to treat population with secondary outcomes including the percentage of patients with haemostasis at 10 minutes and haematoma formation at day 2 following surgery. The time to haemostasis was significantly shorter in the TachoSil® group compared with standard treatment (5.3 minutes (median 3.0, range <3-17) versus 9.5 minutes (median 8.0, range <3-27), respectively; p<0.0001). Haemostasis was achieved in under 10 minutes in significantly more patients in the TachoSil® group (92% versus 67%, p<0.0001). There was no difference between groups in haematoma formation at day 2 or in other secondary efficacy endpoints.

Summary of evidence on comparative safety

No new safety concerns were reported for TachoSil® in this study in kidney resection. The only differences in adverse events between treatment groups were fever and extravasation of urine. Fever was reported in 15 TachoSil® patients compared with seven standard treatment patients and three patients had extravasation of urine in the TachoSil® group compared with none in the standard treatment group, although two of these extravasations were considered unlikely to be related to treatment.

Summary of clinical effectiveness issues

In the key randomised study, TachoSil® has been shown to significantly reduce the time to haemostasis compared with standard treatment. However, it is not licensed to replace standard treatment using suturing but to be in addition when standard treatment has proved insufficient. There is no comparative information for TachoSil® against other fleeces and sealants licensed for this indication. As there is a paucity of robust comparative evidence for supportive treatments for haemostasis in general, it is difficult to assess the merits of TachoSil® compared with other methods. TachoSil® has the practical advantage over other supportive treatments in that it does not require suturing in place and it requires no special storage requirements or preparation before use other than moistening with saline.

Summary of comparative health economic evidence

A cost minimisation analysis was provided by the manufacturer to compare TachoSil® to current clinical practice. Current clinical practice comprised three different treatment strategies, as informed by Scottish expert opinion. Given this, the manufacturer used a weighted average approach to derive an indicative cost of current practice, which seemed a reasonable method to use. TachoSil® was associated with £107.45 of additional product acquisition costs per patient compared to current practice, assuming the use of one large TachoSil® sponge per patient. The analysis also considered the general theatre costs associated with treatment. In the base case, TachoSil® required around 6 minutes less theatre time compared to current practice. Taking account of this reduced the overall additional cost of TachoSil® to £13.80 per patient compared to current practice, based on theatre time costs of £878 per hour.

The results indicate that TachoSil® use would give rise to a relatively small additional cost per patient compared to the average clinical practice in Scotland at present. The modest nature of this additional cost is however affected by the assumptions used in the analysis such as the number of TachoSil® sponges used, the value to the health service of savings in theatre time and the relative composition of the comparator assumed in the analysis.

Summary of patient and public involvement

A Patient Interest Group Submission was not made.

Additional information: previous SMC advice

In May 2005, after a full submission the Scottish Medicines Consortium recommended that TachoSil is accepted for use within NHS Scotland for the improvement of haemostasis in liver surgery where standard techniques are insufficient.

Additional information: comparators

Quixil® Human Surgical Sealant, FloSeal® Matrix Haemostatic Sealant, Surgicel®

Additional information: costs

Product	No of applications	Cost (£)
[*]Tachosil®	**1-3 sponges**	**190-570**
Quixil™ Human Surgical Sealant	5-10ml	379-778
FloSeal™ Matrix	5ml	150
Surgicel®	5x7.5cm 10xx20cm	11.07 28.23

Current costs for these products were not available from eVadis and therefore company list prices were used.
*SPC states that the typical number of sponges used in clinical studies was 1-3
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Additional information: budget impact

The manufacturer presented a range of scenarios based on different market penetration estimates. If Tachosil® is used in 20% of eligible kidney resections then the net additional acquisition costs are £847 in year one (8 patients) rising to £1161 by year five (11 patients) compared to the weighted average cost of current clinical practice. If Tachosil® is used in 50% of eligible patients then the additional acquisition costs are £2118 in year one (20 patients) and £2903 by year five (27 patients). If Tachosil® is used in all eligible patients then the comparable figures would be £4235 and £5805 respectively. These estimates assume that one large Tachosil® sponge is used per patient. The budget impact for use in other types of surgery has not been estimated.

Advice context:

No part of this advice may be used without the whole of the advice being quoted in full.

This advice represents the view of the Scottish Medicines Consortium and was arrived at after careful consideration and evaluation of the available evidence. It is provided to inform the considerations of Area Drug & Therapeutics Committees and NHS Boards in Scotland in determining medicines for local use or local formulary inclusion. This advice does not override the individual responsibility of health professionals to make decisions in the exercise of their clinical judgement in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

This assessment is based on data submitted by the applicant company up to and including 4 January 2007.

Drug prices are those available at the time the papers were issued to SMC for consideration. These have been confirmed from the eVadis drug database.