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Technology Assessment Unit of the McGill
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Argon beam coagulation in orthopaedic, urological and thoracic surgery at the MUHC:

A brief report

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BACKGROUND

The Orthopaedics, Urology, and Thoracic divisions of the Department of Surgery at the McGill University Health Centre (MUHC) have jointly requested purchase of an electrosurgical generator with argon beam coagulator (ABC) capability for use in the operating room of the Montreal General Hospital. This technology assessment report was carried out at the request of Donna Stanbridge, Chair, Operating Room Product Approval Committee (ORPAC).

ABC is used for two quite different objectives: 1) to secure haemostasis and to obtain better surgical visibility during surgery, and 2) as an adjuvant therapy following surgery for bone tumours. In this report we consider only its use in the three areas for which the technology has been requested at the MUHC:

i) Orthopaedics: In orthopaedics ABC will be used for three procedures: 1) For extensive soft tissue resection and amputation, 2) To treat the cavity after removal of bone tumours with the objective of reducing recurrence rates. 3) It might also be used for arthroscopic procedures where cauterisation is needed.[1]

ii) Urology: In urology ABC will be used for partial nephrectomy procedures, to secure haemostasis by uniformly coagulating the resected surface of the kidney. It may also reduce the formation of eschar that may become dislodged post-operatively and cause post-operative haemorrhage[1]. It may also possibly eradicate residual tumour cells, thus reducing the risk of local recurrence.[1,2] It may also be used to control surface oozing during open radical prostatectomy cases.

iii) Thoracic Surgery: The ABC system may be used for extra-pleural thoracotomy pneumonectomy to prevent profuse bleeding through meticulous haemostasis.[3]

Two argon beam coagulation units are already in use at the MUHC. One is located in the operating room of the Royal Victoria Hospital, where it is used in liver transplant surgery. The second is used in the Gastroenterology unit at the Montreal General Hospital; however, this unit is not suitable for laparascopic procedures. In addition, two electrosurgical units that are argon-capable (i.e. can be extended to include argon beam coagulation) are in use in the MGH operating room (Model ICC 300, manufactured by ERBE).

METHOD

To identify evidence of the potential value of ABC in the context of these three applications, we consulted clinical users of the technology and conducted a literature search (Appendix 1). The systematic search identified 7 relevant review articles and 4 case report/series. We found no health technology assessment reports, systematic reviews or peer-reviewed randomized controlled trials on the use of ABC in orthopaedic, urological or thoracic procedures. We found 1 controlled cohort study investigating the use of ABC following the curettage of aneurysmal bone cysts.[4] We also found 1 uncontrolled study of ABC in patients with giant cell tumour[5] and 1 conference presentation based on a randomized controlled trial comparing phenol to ABC for the treatment of bone tumours.[6]

RESULTS

Haemostasis.

ABC achieves haemostasis without making direct contact with the tissue, thus reducing the possibility of charring. It also allows better visualization because of the smaller smoke plumes. The depth of tissue coagulation achieved by ABC is approximately 2 mm, which could be deepened by varying the output power of the electrosurgical generator and the duration of application. Typically, low power and low argon flow rates are used for haemostasis, while higher output settings are used for tissue ablation.[2]

There are alternative technologies that can be used for achieving haemostasis such as the bipolar coagulation forceps and various haemostatic agents.[7] The advantage of bipolar coagulation forceps is that it can be used for simultaneous dissection and haemostasis. Numerous haemostatic agents are also available (Surgicel and FloSeal are currently used at the MUHC) to cover the nephrectomy defect and to reconstruct the kidney after resection.[7] A cohort study by Gill et al.[8] comparing outcomes with FloSeal use (63 patients) and without (68 patients), found that it reduced the risk of haemorrhagic complications (12% vs. 3%) as well as urine leaks (1.5% vs. 6%). A survey of 18 major academic centres (1347 patients) in Europe and the United States found that haemostatic agents were used in 16 centres (1042 patients, (77%)) in addition to performing concomitant suturing of the nephrectomy bed.[9] The authors concluded that the use of haemostatic agents

was becoming standard at most centres. They also observed that the risk of post-operative haemorrhage requiring transfusion (2.7%) and the risk of urinary leakage (1.9%) were low at the participating centres.

Adjuvant.

In addition to its use as an effective haemostatic agent, ABC has also been considered as a potential adjuvant treatment for bone tumours, especially Giant Cell Tumour. The term adjuvant treatment refers to the use of any agent applied to the bone cavity following tumour removal and curettage that may eradicate residual tumour cells and thus reduce local recurrence rates. Such agents include liquid nitrogen, phenol and alcohol, hydrogen peroxide, heat cauterisation with electrocautery and polymethyl-methacrylate polymerisation.[5] Currently, at the MUHC, phenol is used for this purpose.

Adjuvant treatments are reported to decrease recurrence rates.[5, 10-12] However, not all agree. For example, Turcotte with the Canadian, Sarcoma Study Group[13] carried out a retrospective study of 186 cases (158 primary, 28 recurrences) with a minimum follow-up of 24 months. Of these, 148 had curettage, supplemented with high-speed burring in 135, cement in 64, bone grafts in 61, phenol in 37, and liquid nitrogen in 10. The overall recurrence rate was 17%, (after curettage 18%, and after resection 16%). They also concluded that the type of adjuvant method use failed to show any statistical impact on the recurrence risk.

The evidence supporting the use of ABC for this purpose consists of two published studies,[4, 5] and one conference presentation.[6] These concur that use of ABC as an adjuvant therapy is associated with low recurrence rates that are comparable to other adjuvant treatments, and that it is safe and convenient to use. These studies are summarized in Appendix 2.

Safety.

The current literature has described ABC as generally safe.[4-6] One concern with using ABC for laparascopic partial nephrectomy is that it can cause a dangerous elevation in intra-abdominal pressure leading to gas embolism or tension pneumothorax.[2, 7] There is one report of ABC-induced pneumothorax in a 5-year-old

female during laparoscopic partial nephrectomy.[14] This can be avoided by venting through the trocar and active suctioning with a laparascopic suction cannula.

The cost of an electrosurgical unit with argon beam capability (ABC) is approximately $50,000. Assuming each unit would have a service life of 15 years, and an annual discount rate of 5%, we estimated the equivalent annual cost (EAC) to be $4,817.

Based on the ORPAC request form[1] the estimated number of procedures and annual cost of disposables for the CONMED unit are shown in the table below.

	ORTHOPAEDICS		UROLOGY	THORACIC	Total
Total procedures/ year	45*	15**	48	12	120
Unit price of disposables ($)	350.00	300.00	180.00	300.00	
Cost of disposables/Yr ($)	15,750.00	4,500.00	8,640	3,600	32,490.00
Ammortized capital cost ($)	1,806.00	602.00	1,927.00	482.00	4,817.00
Cost/procedure ($)	390.00	340.00	220.00	340.00	
Total Cost per year ($)	17,556.00	5,102.00	10,567.00	4,082.00	37,307.00

*ABC triple action handcontrol.

**6” bend a beam malleable handcontrol.

Assuming that the number of procedures per year does not change (120 per year), the ammortized capital costs will contribute $40 to the cost of each procedure. The annual total budget impact would be **$37,307,** and the cost per procedure would range from $220 to $390. Based on the same ORPAC request form [1] the cost of the products currently used if applied to the same number of cases would total $16,477 per year. Thus the net annual increase in expenditure from the use of ABC would be approximately **$20,830**.

The ERBE unit employs reusable applicators and may therefore be less expensive. It is also more compact, occupying less space in the OR.

CONCLUSIONS

- In spite of its availability for over two decades there is a paucity of clinical evidence concerning the usefulness of ABC in orthopaedic, urological, or thoracic surgery
- ABC technology is widely used in other areas, such as gastrointestinal endoscopy and liver transplantation in numerous institutions, including the MUHC.
- Based on input from clinical review articles and consultation with MUHC faculty, it is apparent that ABC is not imperative for any of the procedures for which it has been requested. Its use is largely determined by individual physician preference. For example, at the University Hospital Network in Toronto argon beam coagulation is used in thoracic surgery, but not in urology or orthopaedic surgery. At the Centre Hospitalier de l'Université de Montréal (CHUM) it is not used for orthopaedic, urological or thoracic surgical procedures.
- For haemostasis alternative options exist in all three areas considered, and are already available at the MUHC. Nevertheless, some surgeons find argon beam coagulation superior for particular procedures.
- For use as an adjuvant following surgical excision of bone tumours there is limited evidence, (of very poor quality) that its use will lower tumour recurrence rates. Compared to other treatments such as liquid nitrogen and cryotherapy, it is safer and easier to use.
- With ammortization of the cost of the generator, and assuming the predicted usage rates, ABC will cost the MUHC approximately $20,000 (net) per year.

RECOMMENDATIONS

In coming to a decision on this issue the Surgical Mission should take the following points into consideration :

- **Some surgeons believe that the availability of ABC in the operating room may result in better surgical outcomes.**
- **The budget impact of approving this acquisition would be relatively modest, approximately $20,000 a year.**
- **Before undertaking any permanent purchase, the possibility of converting existing equipment should be explored.**

- **If such conversion is not feasible this technology should initially be acquired on a short-term basis to allow for its evaluation by different interested surgeons.**

REFERENCES

(1) Stanbridge D, Turcotte R, Andonian S, Kassouf, Tanguay, Sirois. MUHC ORPAC Request Form - Request #46: Argon beam electrosurgical unit. 2010.

(2) Ramanathan R, Leveillee R. A review of methods for hemostasis and renorrhaphy after laparoscopic and robot-assised laparoscopic partial nephrectomy. *Curr Urol Rep* 2010;11(3):208-220.

(3) Opitz I, Kestenholz P, Lardinois D et al. Incidence and management of complications after neoadjuvant chemotherapy followed by extrapleural pneumonectomy for malignant pleural mesothelioma. *European Journal of Cardio-thoracic Surgery* 2006;29:579-584.

(4) Cummings J, Smith R, Heck R. Argon Beam Coagulation as Adjuvant Treatment after Curettage of Aneurysmal Bone Cysts. *Clin Orthop Relat Res* 2010;468:231-237.

(5) Lewis V, Wei A, Mendoza T, Primus F, Peabody T, Simon M. Argon beam coagulation as an adjuvant for local control of giant cell tumour. *Clin Ortho Relat Res* 2006;454:192-197.

(6) Uglialoro A, Benevenia J, Patterson F, Beebe K. Phenol vs. argon beam used as adjuvants in the treatments of stage 2 & 3 (benign-aggressive) bone tumours presented at Musculoskeletal Tumour SocietyAnnual Meeting. Phoenix, Arizona: 2008. 2008.

(7) Andonian S, Janetschek G, Lee BR. Laparoscopic partial nephrectomy: an update on contemporary issues. *Urol Clin North Am* 2008;35(3):385-396.

(8) Gill I, Ramani A, Sapaliviero M et al. Improved haemostasis during laparoscopic partial nephrectomy using gelatin matrix thrombin sealant. *Urology* 2005;65(3):463-466.

(9) Breda A, Stepanian S, Lam J et al. Use of haemostatic agents and glues during laparoscopic partial nephrectomy: a multi-institutional survey from the United States and Europe of 1347 cases. *Eur Urol* 2007;52(3):798-803.

(10) Balke M, Schremper L, Gebert C et al. Giant cell tumour of bone: treatment and outcome of 240 cases. *J Cancer Res Clin Oncol* 2008;134:969-978.

(11) Goodman H, Benevenia J. Adjuvant treatment of non-malignant active and aggressive bone tumours. *Current Orthopaedic Practice* 2009;20:610-615.

(12) Malarwer M, Bickels J, Meller J, Buch R, Henshaw R, Kollender Y. Cryosurgery in the treatment of giant cell tumour. *Clinical Orthopaedics and Related Research* 1999;359:179-188.

(13) Turcotte R, Wunder J, Isler M et al. Giant Cell Tumour of Long Bone: A Canadian Sarcoma Group Study. *Clin Ortho Relat Res* 2002;397:248-258.

(14) Shanberg A, Zagnoev M, Clougherty T. Tension pneumothorax caused by the argon beam coagulator during laparoscopic partial nephrectomy. *J Urol* 2002;168:2162.

APPENDICES

APPENDIX 1. Search strategies and outcome

A search for Health Technology Assessments and systematic reviews of argon beam coagulation and its variations, including argon gas and argon plasma coagulation, was performed using the University of York's Centre for Reviews and Dissemination online databases. Ovid Medline, NSAW Clinical Register, and EMBASE databases were searched for relevant randomized controlled trials. The bibliographies of published articles were also used. Keywords used included "argon beam OR argon gas OR argon plasma coagulation" and "randomized controlled trial." Search returns were further narrowed down to focus on orthopaedics, thoracic, and urology disciplines. Searches were not limited by language or year of publication encompassing all publications published up to November 17, 2010. The literature search as well as the review of the articles was performed independently by two authors (IP and ND).

APPENDIX 2.

Summary of reports on the efficacy of argon beam coagulation as adjuvant therapy.

1. Cummings et al., 2010[4]

Objective: To compare aneurismal bone cysts recurrence rate between patients who received argon beam coagulation or no adjuvant treatment following the curettage.

Study design: Retrospective review of 40 charts (11 dropouts) diagnosed with aneurysmal bone cysts.

Patients: Patients who had primary aneurysmal bone cyst, underwent curettage. Includes children under 18 (age range 4-39, average 12.2 years old). Minimum follow-up time of 18 months.

Methods: 17 patients underwent curettage plus ABC, another 12 patients received curettage only or with phenol.

Results: No local recurrence of bone cyst was seen in all 17 patients who were treated with adjuvant ABC (0% local recurrence). On the other hand, local recurrence was observed in four of those who did not receive adjuvant ABC (Difference in risk 33% (95% confidence interval: 6%, 61%)). No ABC-related adverse event was observed.

Conclusion: Argon beam coagulation appears to be a safe and effective adjuvant treatment following bone cyst curettage in reducing cyst recurrence.

2. Lewis et al., 2006[5]

Objective: To assess the efficacy of argon beam coagulation in preventing recurrence of local giant cell tumour (GCT) when used as an adjuvant treatment.

Study design: Retrospective cohort study by chart review, uncontrolled

Patients: Patients with GCT operated with curettage. Total cohort included 37 patients, 68% male, median age 32 years (16-64) and the average follow-up time was 74 months (0.5-108).

Methods: All 37 patients underwent curettage plus ABC.

Results Tumour recurred in 4/37 patients (10.25%); mean recurrence time was 18 months. Kaplan-Meier survival curve indicated an 87.2% (95% CI, 76.3-99.8%) 5-year no recurrence rate in the cohort. Patients who had preoperative, pathologic fracture had increased recurrence ($p<0.001$). Overall postoperative complications were observed in 10/37 patients (27%). In addition, average Musculoskeletal Tumour Society (MSTS) score was 28. No change in functional or mental state was discovered in patients.

Conclusion Argon beam coagulation as an adjuvant treatment following curettage is associated with a low recurrence rate comparable to that obtained with other adjuvant treatments such as phenol or cryotherapy.

3. Uglialoro et al., 2008 (Conference presentation)[6]

Objective To compare phenol and argon beam coagulator as adjuvant therapies in treating stage 2 & 3 bone tumours.

Study design Randomized controlled trial

Patients Patients operated for benign-aggressive bone tumours, followed up for 54 months (10-168).

Methods 41 patients were randomized to receive phenol, 61 received ABC.

Results There was no difference in recurrence rate between the phenol (7/41, 17.1%) and ABC (9/61, 14.8%) groups. Group averages of the MSTS score were comparable, too.

Conclusion While avoiding the difficulties in handling the toxic effects of phenol, our results indicate that argon beam coagulation provides for statistically equivalent recurrence rates in the treatment of benign aggressive bone tumours.