

## Original Article

# Could Harmonic Scalpel (Ultracision®) be considered the best device in surgical treatment of vulvar cancer of patients with implanted pace-maker? Proposal and rationale

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**Abstract:** Vulvar cancer (VC) represents about 4% of gynecologic malignancies, its incidence increases with age and peak incidence is found between 70-79 years. In cases of locally advanced disease surgery is often required and radical vulvectomy, with or without mono-bilateral inguino-femoral lymphadenectomy, is standard management. Various devices have been implemented in gynecological surgery in an attempt to minimize or avoid frequent intra/postoperative complications linked to energy use, unfortunately the majority of these devices require monopolar or bipolar energy. Ultracision® represents a unique surgical device capable of performing both cutting and coagulation at different intensities without use of electric energy. The use of Ultracision® in the radical treatment of VC has advantages both in terms of intraoperative and postoperative complications responsible for the reduction of surgical time and blood loss, complete tissue removal according to oncological criteria, diminished desensitization of peripheral areas and reduction of wound complications. These advantages have been widely demonstrated and contribute to making Ultracision® a cost-effective option in the routine treatment of patients affected by vulvar cancer especially when considering its safety in cardiopathic patients with implanted pacemaker. If the impressive results achieved in radical vulvar surgery will be confirmed, scalpel use could be proposed as routine for surgery of the routinely in surgical approach of vulvar and perineal area, in both benign and malignant disease.

**Keywords:** Harmonic Scalpel, Ultracision®, surgical device, surgical safety, gold standard, pacemaker, surgical management

### Short communication

Carcinoma of the vulva represents about 4% of gynecologic malignancies, its incidence increases with age and peak incidence is found between 70-79 years [1, 2].

During the past years, the incidence of VC in young women increased in part due to its association with HPV infection since 40-60% of VC are HPV related. Consequently the introduction of HPV 16 and 18 immunizations should reduce the incidence of VC in young women and in a long term perspective also in elderly women [1, 3].

Surgical treatment of VC is based on the assumption of radial progressive tumor perme-

ation; the labia majora and mons pubis are considered as part of the vulva whereas the perineum and anus are considered distinct. The concept of radial progressive tumor permeation implies the advancement of microscopic and occult disease preceding the macroscopic tumor front in all directions, particularly by lymph vascular space involvement [4, 5].

Recent theories propose to revisit surgical therapy for local tumor control on the basis of morphogenesis considering ontogenetic anatomy [5].

To decrease psychosexual morbidity, a more conservative approach than radical vulvectomy is usually indicated. The procedure may be identified in a radical wide local excision, and

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for localized lesions, this approach is as effective as radical vulvectomy in preventing local recurrence [6].

However, in locally advanced disease or recurrence after local excision and in patients with long life expectancy, surgery with curative intent often requires radical vulvectomy and mono-bilateral lymphadenectomy.

Contrarily to local excision or partial vulvectomy, the surgical approach with radical intent is usually affected by an increased risk of intra-operative and perioperative complications such as high blood loss, prolonged anesthesia due to increased surgical time, wound breakdown/infections/difficult healing, lymph-cyst formation and lymphedema (due to inguino-femoral radical lymphadenectomy) [7].

Radical vulvectomy may represent a challenge for gynecologic Surgeons since it is rarely performed, patients are often older and affected by comorbidities. Moreover, surgical debulking has significant esthetic and psychosexual implications. The surgical dilemma occurs when VC is diagnosed in patients with a medical history of previous pacemaker implantation and a relatively long life expectancy.

In this peculiar cohort of patients, the use of electrosurgery (especially monopolar) can cause severe complications such as oversensing (inappropriate inhibition of pacing output), resetting of rhythm and damage to the device [8].

Although bipolar electrosurgery appears to have a minimal chance of adverse interaction with the device, it is used less commonly than monopolar energy since it is only indicated for coagulation and not dissection [9, 10].

The risk of electrosurgery can be managed by a dedicated team of anesthesiologists and nurses that provides by placing a magnet over the defibrillator or reprogramming to an asynchronous mode.

The reprogramming option leaves the operative team free from the concern of magnet location and possible malfunctioning. On the other hand, the principal disadvantage of the reprogramming option is that the changes made are not readily reversible as well as any further change (possibly linked to incompatibility

between the new program and an emerging arrhythmia) need the presence of the programmer in the operating room [8].

The magnet must be quickly removed in order to treat a tachyarrhythmia or to allow an external cardioversion and, despite its proven efficacy, it requires a dedicated team implying a risk comparable to the reprogramming option [8].

Various devices have been implemented in gynecological surgery in an attempt to minimize or avoid frequent intra/postoperative complications linked to energy use, unfortunately the majority of these devices require monopolar or bipolar energy [11-15].

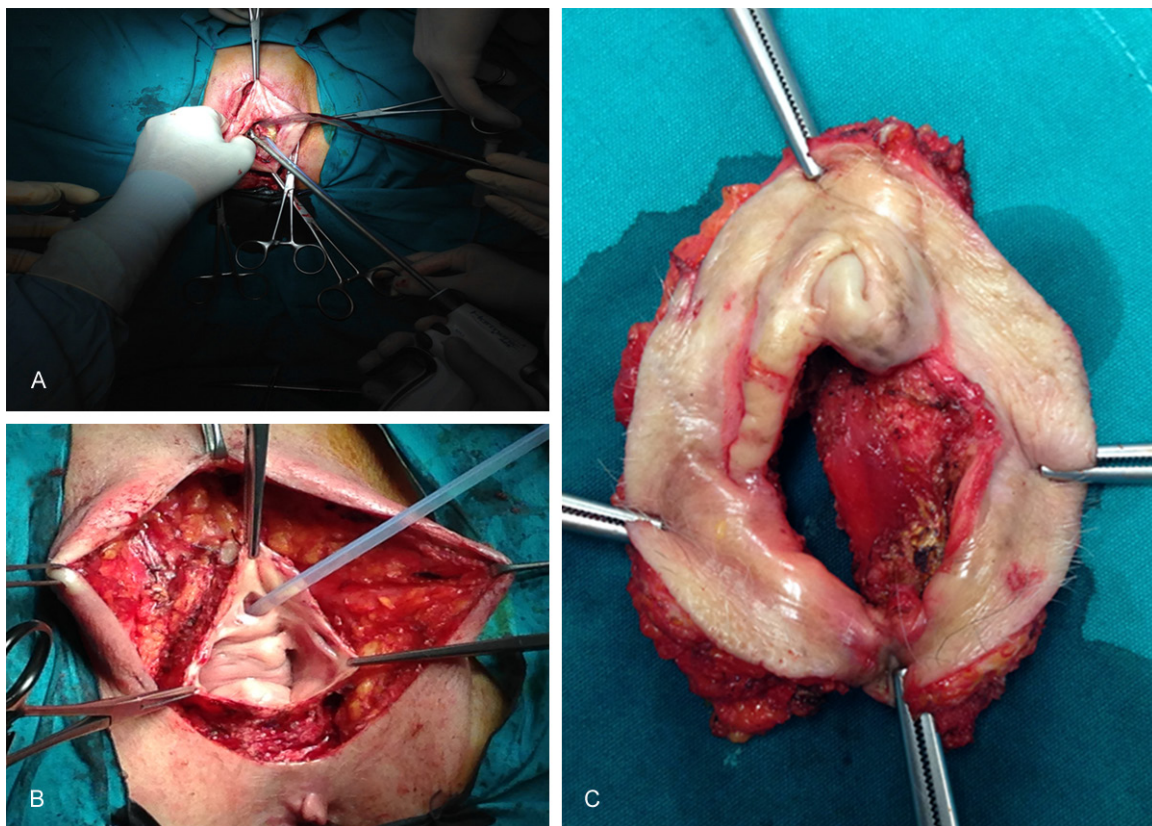
Ultracision® (Ethicon Endo-Surgery Inc, Cincinnati, OH, USA) represents a unique surgical device capable of performing both cutting and coagulation at different intensities without the use of electric energy.

The Harmonic scalpel incorporates piezoelectric transducers that induce a vibration frequency at the functional tip and transduces a lower amount of energy to the tissue controlling bleeding through the process of coactive coagulation [16, 17].

The advantages of the Harmonic scalpel can be explained by analyzing its mechanism of action. There is no passage of electric energy through the patient's body, similarly to the MRgFUS technique employed in the treatment of myomas [18, 19].

The harmonic scalpel operates at lower temperatures than electrosurgical devices by denaturing proteins through mechanically breaking the hydrogen bonds in molecules thus generating much less heat from tissue friction. The relatively low temperature generated by the Ultracision® device and the subsequently low level of thermal energy transferred to the adjacent tissues avoids the necrosis of surgical margins thus limiting the risk of wound complications [20-22].

However, high-power ultrasonic dissection lasting more than 10 seconds may result in considerable heat production and collateral tissue damage, especially when the activation time exceeds 10 seconds [23].



**Figure 1.** Pictures of Harmonic Scalpel (Ultracision®) use during radical vulvectomy in patients with implanted pace-maker. (A: Vulvar dissection phase; B: Anatomic dissection plans after radical vulvar removal; C: Macroscopic features of vulvar specimen).

From an exclusively surgical point of view, there are proven advantages linked to the use of Ultracision®: reduced duration of surgery (linked to a simplification of the surgical gesture), reduced blood loss (also linked to the reduced operative times) no smoke and no energy passage through the patient's body (which thus allows for use on patients with implanted pacemaker) [21, 22].

Lateral thermal spread with Ultracision was found to be at maximum 1.6 mm beyond the tissue bundle or vessel, which confers certain advantages during lymphadenectomy in reducing iatrogenic damage to adjacent inguinal vascular structures [21, 22].

Furthermore iatrogenic nerve injury has been observed to be significantly inferior in Ultracision® use as opposed to the application of monopolar/bipolar surgical devices [24].

The use of Ultracision® in the radical treatment of VC has advantages both in terms of intraoperative and postoperative complications

responsible for the reduction of surgical time and blood loss, complete tissue removal according to oncological criteria, diminished desensitization of peripheral areas and reduction of wound complications.

These advantages have been extensively demonstrated and seem to make Ultracision® a cost-effective option in the routine treatment of patients affected by vulvar cancer particularly in consideration of its safety in cardiopathic patient a with pacemaker implant.

Our experience agrees with the interesting data available regarding Scalpel use in radical vulvectomy, both in term of early and long-term advantages related to oncological, functional and esthetic results. All cases treated in our Units by Harmonic scalpel reported high satisfaction rate due to the low/absent impairment in of their quality of life and good esthetic outcomes (**Figure 1A-C**).

By proposing Ultracision® as an elective device for the treatment of VC, we could provide data

regarding its use, safety and advantages thus overcoming the difficulties due to the low incidence of this neoplasia.

If the exciting results achieved in radical vulvar surgery will be confirmed, scalpel use could be proposed routinely in the surgeries of the vulvar and perineal area.

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## Disclosure of conflict of interest

None.

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