

# PRIMARY IMIQUIMOD TREATMENT VERSUS SURGERY FOR VULVAR INTRAEPITHELIAL NEOPLASIA – PITVIN STUDY. BASELINE RESULTS OF A RANDOMIZED CLINICAL TRIAL

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**Introduction/Background** Usual type vulvar intraepithelial neoplasia (u-VIN) is a premalignant condition of the squamous epithelium of the vulva caused by persistent infection with high-risk human papillomavirus (HPV), and classified as high grade squamous intraepithelial lesion (HSIL). Surgery is the standard treatment, but recurrences occur in about 50% of patients. Imiquimod, a topical immune response modifier, has been shown to be effective, but has not been compared to surgery. The aim of this study was to compare the effectiveness and acceptance of primary imiquimod treatment with surgical treatment of HSIL/VIN.

**Methodology** This was a multicentre randomised controlled trial of women with histologically confirmed HSIL/VIN II-III. Exclusion criteria were clinical suspicion of microinvasion, a history of vulvar cancer, severe dermatosis, pregnancy, and any active treatment for VIN within the previous three months.

Patients were randomized to primary topical treatment or surgery at a ratio of 1:1 and stratified by unifocal or multifocal disease. Treatment with imiquimod was self-administered for a period of 4 months with possible extension. Surgical treatment was performed according to the standard procedures of the trial site. Clinical assessment, colposcopy, vulvar punch-biopsy and HPV-test (cobas®, Roche) were performed at baseline and 6 months. Clinical follow-up, including questionnaires on health-related quality-of-life, was conducted at 12 months.

**Results** Between June 2013 and January 2020 a total of 110 patients were enrolled at six hospitals in Austria. Mean age was 51 years (SD 16, range 19 -82) with 57% being postmenopausal. 66 patients (61%) had a history of previous HPV related anogenital HSIL or genital warts, and 21 women (19%) had received previous treatment for VIN. 85 women (78%) presented with unifocal and 24 (22%) with multifocal VIN, and 56 women (51%) reported local symptoms. 40 women (37%) had a history of current or past smoking. 56 women were allocated to primary treatment with imiquimod, and 54 women to primary surgery. Surgical treatment was performed by local excision in 22 cases (14 cold-knife, 6 electro-surgical), by laser destruction (n= 27), or combined (n=3). 12-months follow-up will be completed in January 2021.

**Conclusion** The results of this clinical trial will show whether imiquimod is a safe and effective alternative to surgery in women with HSIL/VIN2-3.

**Disclosures** The study was funded by the Austrian Science Fund (FWF) and the Austrian Association for Gynecologic Oncology (AGO). The study medication Aldara 5% cream was provided by Meda Pharma GmbH. The authors have no conflict of interest.

## Organization of gynaecological cancer care

### IMPLEMENTATION, PRACTISE AND EXPERIENCES OF AN INTERNATIONAL ONLINE MULTIDISCIPLINARY TUMOUR BOARD (IMDTB) WITH A CANCER CENTRE IN NORTHWEST REGION OF CAMEROON

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**Introduction/Background** Multidisciplinary tumour boards (MDTBs) are universally recommended. Nevertheless access to MDTBs, especially in low-income countries and rural areas, is limited. In order to gain insight in its efficiency and in its impact on quality of cancer care this study has been performed on the international multidisciplinary (video-) online tumour board (iMDTB) established by Camfomedics e.V. and its partners Mephida e.V. and Global Health Catalyst Summit @ Harvard with a cancer centre in northwest region of Cameroon, the Mbingo Baptist Hospital.

**Methodology** Patient's data of all cases of 2019 of the Camfomedics-iMDTB have been collected and evaluated in regard of disease, age, sex, stage, recommendation and level of available care.

Furthermore an online survey among participants of the Camfomedics-iMDTB on their practises, experiences and satisfaction with the iMDTB has been undertaken.

**Results** International multidisciplinary tumour board was scheduled monthly with online video meeting times of 60 to 90 mins. In 2019 during 12 meetings 95 tumour cases had been discussed. The majority of patients (75%) were female. 24% of all tumour cases were breast cancer followed by cervical cancer with 10%. Remarkably anorectal carcinomas and sarcomas occurred with a percentage of 7–8% each. Furthermore three women out of 72 suffered from high risk trophoblastic tumours.

66% of cases could be presented with a proper TNM-classification. More than half of these patients were already in a late stage of their disease (extended, metastatic or high risk). Pathology results were limited to microscopy for most cases. Additional diagnostics (such as hormone receptor status, HER2neu status) were available only in a minority of the cases. Treatment plans had been changed in up to 50% of cases.

The tumour board members describe their experience with the online conferences, data and documentation quality as satisfactory.

**Conclusion** The iMDTB of Camfomedics is a helpful and effective way to improve cancer care in low income countries and rural areas such as the northwest region of Cameroon. The tumour board's success very much depends on the charitable attendance of its specialists and the local (human) resources for time consuming preparation. Main challenges remain foremost the patients' ability to afford expensive cancer

diagnostics and therapies, local availability of medical, surgical and radiological treatment as well as a stable online video connection. The iMDTB has a significant impact not only on multidisciplinary of cancer management in the cooperating institutions but also on social values and education of the participants.

Disclosures None.

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# CENTRE OF HEREDITARY BREAST AND OVARIAN CANCER AT CHARITÉ – WHO PRESENTS FOR COUNSELING AND WHY?

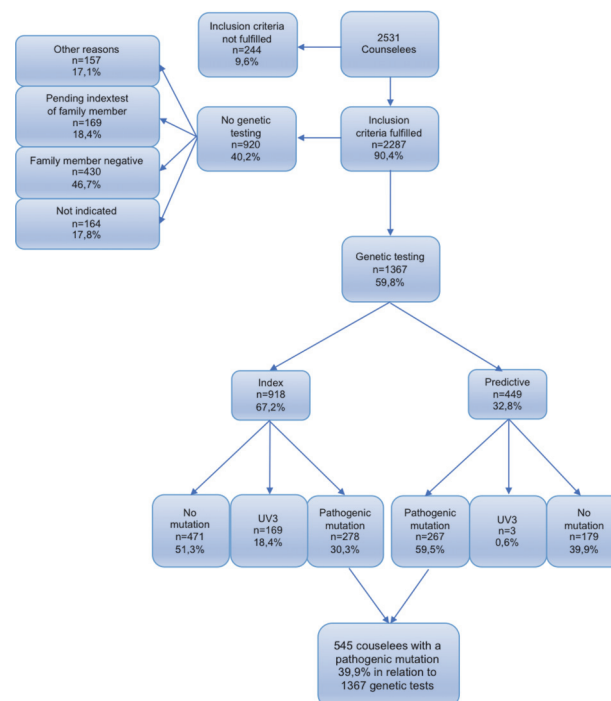
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**Introduction/Background** Since the discovery of the BRCA-genes the knowledge about genetic risk factors for breast and ovarian cancer has multiplied. About 5–10% of all breast cancers and 15–20% of all ovarian cancers are caused by pathogenic mutations in different risk genes. Therefore, the Centre of Hereditary Breast and Ovarian Cancer at Charité offers as one of 20 centres in Germany genetic counseling. The extensive data of the counselees was now evaluated for the first time. The aim of this study was to ease the preparation for counseling sessions and gather information for more individualized counseling.

**Methodology** Data from 2531 counselees at the Charité-Centre from 2016 and 2017 were evaluated retrospectively. Special emphasis was laid on sociodemographic data and the results of genetic testing. Finally, the mutation frequencies were analyzed in different subgroups.

**Results** The 2531 counselees were almost exclusively female ( $n = 2493$ ; 98.5%), 42.9 years old on average and came to the centre for the first time ( $n = 2198$ ; 86.8%). 2287 (90.4%) counselees met the inclusion criteria for genetic testing. Of these, 863 (37.7%) were already diagnosed with breast or ovarian cancer. 1367 (59.8%) were genetically tested, 918 (67.2%) as index patients and 449 (32.8%) predictively. Mutations were detected in 545 (39.9%) tested persons. Most mutations were detected in BRCA1, BRCA2, CHEK2 and ATM. The highest mutation frequency was found among persons from families with both breast and ovarian cancer and in



**Abstract 139 Figure 1** Flow chart of the results of the genetic testing

patients with TNBC. A significant correlation was found between mutation frequency in TNBC and age at first diagnosis (figure 1).

**Conclusion** In summary, the collective of counselees at the Charité-Center was described for the first time. The results provide doctors with a comprehensive overview of the counselees, enabling by that an even more individualized counseling and more focused preparation for the consultation.

The findings contribute to maintaining the high quality of the genetic counseling at the Centre for Familial Breast and Ovarian Cancer at the Charité (table 1).

Disclosures No conflict of interest.

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# WHEN MDT INTERDISCIPLINARITY ENHANCES STRINGENCY AND PROFESSIONAL QUALITY; AN ANALYSIS OF MULTI-DISCIPLINARY TEAM CONFERENCES

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**Introduction/Background** In 2016 the Danish Multidisciplinary Cancer Group's (DMCG) national Multidisciplinary Team (MDT) working committee established recommended quality standards in Danish healthcare.

This current study investigates the status of implementation of the guideline published in 2016 amongst the clinicians who

**Abstract 139 Table 1** Cancer specifics and age at first diagnosis

	Counselees who met the inclusion criteria	
	n=2287	(100%)
<b>Malignant tumor disease</b>		
No tumor	1387	(60,6%)
Breast cancer	787	(34,4%)
ER/PgR/HER2-positive	562	(24,6%)
triple-negative	180	(7,9%)
DCIS	41	(1,8%)
male breast cancer	4	(0,2%)
Ovarian cancer	76	(3,3%)
Other malignant tumor disease	37	(1,6%)
<b>Age at first diagnosis, mean in years</b>		
Breast cancer	44,4	(24-83 years)
Ovarian cancer	50,8	(17-75 years)