337

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 punchbiopsy 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 electrosurgical), 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.

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Organization of gynaecological cancer care

43

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

A108