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Poster Presentation

38 YEARS OF EXCELLENCE IN MEDICAL PUBLISHING

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Audit of the Gynaecological Cancer Pathway Breaches in Ysbyty Gwynedd

Georgia Mills
Betsi Cadwaladr Health Board, United Kingdom

The aim of this audit is to examine how well Ysbyty Gwynedd are keeping to national standards with regards to the urgent suspected cancer pathway for gynaecological cancer.

Up until 2021, the Urgent Suspected Cancer (USC) pathway was used for GP referrals and the Non-Urgent Suspected Cancer (NUSC) pathway for alternative routes. There were reported issues with these pathways so a new streamlined pathway was made called the single cancer pathway (SCP).

Data for the audit was collected at Ysbyty Gwynedd. I assessed all patients diagnosed with a gynaecological cancer (ovarian, uterine, cervical or vulval) between June and December 2020. I used Patient Information Management System (PIMS) and Patient Information System (PAS).

41 patients were diagnosed with a gynaecological cancer in Ysbyty Gwynedd between the first of June and 31st of December 2020. All these patients were referred via the urgent suspected cancer (USC) pathway. 38 patients did not breach the USC pathway of 62 days with 20 patients being <31 days and 18 patients being <62 days. Three people did however breach the USC pathway. This means that 7.3% of patients breached the USC pathway. If using the new pathway, 14.6% of patients would have breached.

The new single cancer pathway is more effective at spotting breaches in quality of care and effective diagnosis. By using this new pathway, it will mean that much more can be done to improve the speed of treatment and therefore improving their short-term and long-term outcomes.

Recent publications

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3. Felix A, Brinton L. Cancer Progress and Priorities: Uterine Cancer. Cancer Epidemiology Biomarkers & Prevention. 2018;27(9):985-994.
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Biography

Georgia Mills is an FY1 in Wrexham Maelor Hospital in Wales. She studied at Cardiff University completing an undergraduate medicine degree in summer 2022. She completed this audit during a reproductive medicine placement as a student.

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Modified Thermal Balloon Endometrial Ablation for Treatment of Heavy Menstrual Bleeding

Baraa Lukman Humo Al Ibrahim, Ahmed Jasim Al Husaynei
Mosul University, Iraq

Statement of the problem: Heavy Menstrual Bleeding (HMB) is the most common type of menstrual bleeding disorder. HMB should be recognized as having a major impact on a woman's quality of life. Furthermore, the impact on health care resources is considerable. In most cases, medical therapy is effective in managing abnormal bleeding, while surgical treatment is normally restricted to women with whom medical treatments have failed. Regarding surgical treatment, until recently, hysterectomy has been the standard treatment for women with menorrhagia unresponsive to medical treatment. However, since the 1980s, minimally invasive procedures to destroy the endometrium (endometrial ablation) have been developed as an efficient and cost effective alternative to hysterectomy.

The original device (ThermaChoice) combines heat and pressure within the uterine cavity to destroy the endometrium and part of the myometrium. The use of Foley's catheter for this purpose has not been fully evaluated. The purpose of this study was to assess the efficacy and safety of modified thermal balloon using Foley's catheter to achieve endometrial ablation in the treatment of HMB in a low-resource setting.

Methodology: Twelve patients with HMB aged 35–55 years underwent modified thermal balloon ablation using Foley's catheter. The procedure was undertaken in the operation theater under general anesthesia/intravenous sedation. Three cycles of modified thermal balloon ablation using Foley's catheter were performed to ablate the endometrium. The time given to each cycle was 7 min. All the cycles were performed in the same setting. The main outcome measures that were studied were reduction in the menstrual flow, the need for further treatment and relief of dysmenorrhea if present.

Findings: Eighty two percent of patients experienced a reasonable reduction in menstrual blood flow at 3 month follow up. Eighteen percent observed no change in bleeding pattern and needed further treatment after failure of the procedure.

Conclusion: Modified thermal balloon ablation with Foley's catheter can be a promising management of HMB in resource poor settings. It is a cost effective alternative to the original endometrial ablation techniques.

Recent publications

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2. Horne AW, Critchley HO. Heavy menstrual bleeding. In: Edmonds DK, editor. Dewhurst's Textbook of Obstetrics and Gynecology. 9th ed. USA & UK: John Wiley and Sons, Ltd; 2018. p. 1277 94.
3. Christine PW. Abnormal uterine bleeding. In: David ML, Kilby MD, editors. Obstetrics and Gynecology. An Evidence Based Text for MRCOG. 3rd ed. Boca Raton, London, New York: Taylor and Francis Group, LLC; 2016. p. 611 9.

Biography

Baraa Lukman Humo Al-Ibrahim, obstetrician and gynecologist, lecturer in College of Medicine- Mosul University. She has good experience in the field of obstetrics and gynecology, aiming for improving women health and wellbeing. She and her colleague have built this model to treat heavy menstrual bleeding effectively with minimum cost. They have built this model after years of experience in research, teaching and patient management both in hospital and education institutions.

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Accepted Abstracts

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Efficacy of a Multi-ingredient Coriolus Versicolor-Based Vaginal Gel in High-Risk HPV Infected Patients: Results of 6 Different Studies

Cortés J[1], Dexeus D[2], Palacios S[3], Serrano L[4], Gajino C[5], Marín E[6], Criscuolo A[7], Riera M[8], Gaslain Y[9]
[1]Private Practice, Palma, Spain
[2]Clínica Ginecológica Women's, Barcelona, Spain
[3]Instituto Palacios de Salud y Medicina de la Mujer, Madrid, Spain
[4]Policlínico HM Gabinete Velázquez, Madrid, Spain
[5]Hospital Materno Infantil Teresa Herrera, A Coruña, Spain
[6]Hospital Álvaro Cunqueiro, Vigo, Spain
[7]Tor Vergata University Hospital, Rome, Italy
[8]Institut Català de la Salut, Barcelona, Spain
[9]Procare Health Iberia, Barcelona, Spain

Objectives: To evaluate the consistency of the efficacy of a multi-ingredient Coriolus versicolor-based vaginal gel, Papilocare®, on High-Risk Human Papillomavirus (HR-HPV) clearance in 6 different studies1.

Methods: Results from 4 independent observational studies (6 month-treatment period with Papilocare®) were compared to results from a randomized, open, parallel, controlled trial (Paloma: NCT04002154)2 and an observational, multicenter, prospective, one-cohort study (PapilOBS: NCT04199260)3.

- Vigo study: Prospective one-cohort (POC). Secondary endpoint (SE), HPV clearance in 86 patients infected by HPV 16 and/or 18.
- Coruña study: Retrospective one-cohort (ROC). Primary endpoint (PE), HPV clearance assessed in 86 medical patients' records.
- Hospitalet study: ROC. PE, Composite efficacy variable (patients with normal cytology and/or HPV clearance) in 91 HR-HPV patients.
- Roma study4: Retrospective controlled. PE, HR-HPV clearance in 183 patients.
- Paloma trial: RCT, SE, HR-HPV clearance in 91 patients.
- PapilOBS study: POC, SE, HR-HPV clearance in 192 patients.

Results: 48% of patients cleared 16/18HPV in Vigo study. 58% of reduction was observed in the number of HR-HPV patients (Coruña) and 72.5% normalized cytology and/or cleared HR-HPV (Hospitalet). 67% HR-HPV clearance was observed (treated group) vs 37.2% (control group), in the Roma study. In the Paloma trial, HR-HPV clearance reached 63% (treated group) vs 40% (control group). 57.4% HR-HPV clearance was observed in the PapilOBS study.

Conclusions: Papilocare® has shown significant consistent rates of efficacy with a 64% of HR-HPV clearance in weighted average in 6 different studies involving more than 700 patients. These data reinforce the beneficial effect in HR-HPV patients.

Recent Publications

1. Serrano, Luis et al. "Efficacy of a Coriolus versicolor-Based Vaginal Gel in Women With Human Papillomavirus-Dependent Cervical Lesions: The PALOMA Study." Journal of lower genital tract disease vol. 25,2 (2021): 130-136.
2. Gaslain Y, et al. 698 Real-life efficacy of a multi-ingredient Coriolus versicolor based vaginal gel in high-risk HPV patients: the PAPILOBS study final results. International Journal of Gynecologic Cancer 2021;31:A314.
3. Criscuolo, Anna Angela et al. "Therapeutic Efficacy of a Coriolus versicolor-Based Vaginal Gel in Women with Cervical Uterine High-Risk HPV Infection: A Retrospective Observational Study." Advances in therapy vol. 38,2 (2021): 1202-1211.

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Effectiveness of a Multi-ingredient Coriolus Versicolor-Based Vaginal Gel in HPV+ and HIV+ Patients: A Pilot Observational Study

Hijona Elósegui, Jesús Joaquín[1], Sanmartín Salinas, Patricia[2]
[1]Servicio de Obstetricia y Ginecología. Complejo Hospitalario de Jaén. Jaén. Spain
[2]Medical Department. Procare Health Iberia, Barcelona, Spain

Background/Objectives: Immunosuppressed human immunodeficiency virus (HIV) -positive patients are at greater risk of incident, persistent, or recurrent human papillomavirus (HPV) infection. They also have lower clearance rate, higher viral load and a marked predisposition for being colonized by several serotypes: all leading to more frequent and severe HPV-dependent lesions1. A Colorius versicolor-based vaginal gel have shown to repair HPV-dependent low-grade cervical lesions and to increase high-risk HPV clearance in immunocompetent HPV-positive patients2.

The aim is to provide evidence about the effectiveness of a multi-ingredient Coriolus versicolor-based vaginal gel on HPV-dependent cervical alterations and HPV clearance in HIV+ patients.

Methods: Pilot, prospective, one-cohort, observational study. 15 HIV-positive patients colonized by HPV in the endocervix region with an anomalous cervicovaginal cytology were included to receive a Coriolus versicolor-based vaginal gel 1 cannula/day for 21 days during first month + 1 cannula/alternate days for 5 months. Analysis of HPV patients with normal cytology and colposcopy image (improved alterations) and patients with HPV cleared (measured using hybrid capture test) is presented. The study was approved by an IRB and informed consent was signed by patients.

Results: The overall HPV clearance and cytological normalization rates were 73.33% and 80%, respectively. Endocervical colonization by HPV also partially cleared in 13.33% of the cases. At the end of the study, the normalization of the colposcopy anomalies associated to HPV was achieved in 55.56%.

Conclusions: Our results suggest that the proposed Coriolus versicolor-based vaginal gel treatment scheme could be an effective therapy in the management of endocervical HPV infection in HIV + patients. Its effects are similar to those obtained in patients without immunosuppression.

Recent Publications

1. Liu G, Sharma M, Tan N, Barnabas RV. HIV-positive women have higher risk of human papilloma virus infection, precancerous lesions and cervical cancer. AIDS. 2018 Mar 27;32(6):795-808
2. Serrano, Luis et al. “Efficacy of a Coriolus versicolor-Based Vaginal Gel in Women With Human Papillomavirus-Dependent Cervical Lesions: The PALOMA Study.” Journal of lower genital tract disease vol. 25,2 (2021): 130-136.
3. Stelzle, Dominik et al. “Estimates of the global burden of cervical cancer associated with HIV.” The Lancet. Global health vol. 9,2 (2021): e161-e169.

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Efficacy of a Multi-ingredient Coriolus versicolor-Based Vaginal Gel in High-Risk HPV Women Over 40 : Sub-analysis of the Paloma Clinical Trial & Papilobs Real-Life Study

Palacios S[1], Cortés J[2], de Santiago[3], Gaslain Y[4]
[1]Instituto Palacios, Salud y Medicina de la Mujer, Spain
[2]Private Practice, Spain
[3]Centro Oncológico MD Anderson, Spain
[4]Procare Health Iberia, Spain

Background/Objectives: HPV clearance and resolution of cervical HPV-dependent lesions become difficult in peri and postmenopausal women. The objective of this analysis was to evaluate the effect of the Papilocare®, a multi-ingredient Coriolus versicolor-based vaginal gel in repairing the High-Risk (HR) HPV-dependent low-grade cervical lesions in women over 40 years.

Methods: Paloma study1,2 (ClinicalTrials.gov NCT04002154) was a multicenter, randomized, open-label, parallel-group, watchful waiting approach-controlled clinical trial. Unvaccinated HPV positive women aged between 30-65 with cytology of ASCUS or LSIL and concordant colposcopy image were randomized into 3 groups:

A) Papilocare® 1 cannula/day for 1 month + 1 cannula/alternate days for 5 months;

B) Papilocare® 1 cannula/day for 3 months + 1 cannula/alternate days for 3 months;

C) Control group: watchful waiting approach. Papilobs study3 (ClinicalTrial.gov: NCT04199260) was an observational, multicenter, prospective, one-cohort study. Vaccinated or not HPV-positive women aged > 25y with vivo cytology of ASCUS or LSIL and concordant colposcopy were included. Patients were treated with Papilocare® 1 cannula/day for 21 days during first month + 1 cannula/alternate days for 5 months. Percentages of patients with normal cytology and concordant colposcopy after 6 months of treatment in the HR-HPV population are presented.

Results: A total of 30 and 68 HR-HPV patients above 40yo were evaluated in Paloma and Papilobs studies, respectively. In the Paloma trial, normal cytology and concordant colposcopy was observed in 90% vs 33% patients in A+B Papilocare® and control groups, respectively, (p=0.003, Fisher test). In the Papilobs study, normal cytology and concordant colposcopy was achieved in 73,5% of patients.

Conclusions: After a 6-month treatment period, Papilocare® showed a clinically robust and statistically significant efficacy in repairing cervical HR-HPV lesions in women over 40 years vs watchful waiting approach. This efficacy was corroborated in the real-life study in more than 2/3 of the HR-HPV patients above 40.

Recent Publications

1. Serrano, Luis et al. “Efficacy of a Coriolus versicolor-Based Vaginal Gel in Women With Human Papillomavirus-Dependent Cervical Lesions: The PALOMA Study.” Journal of lower genital tract disease vol. 25,2 (2021): 130-136.
2. González, Silvia, et al. “Effect of a Coriolus versicolor-based vaginal gel on cervical epithelialization and vaginal microbiota in HPV-positive women: EPICERVIX pilot study”. Academic Journal of Health Science. 2022/37 (2): 139-145.
3. Criscuolo, Anna Angela et al. “Therapeutic Efficacy of a Coriolus versicolor-Based Vaginal Gel in Women with Cervical Uterine High-Risk HPV Infection: A Retrospective Observational Study.” Advances in therapy vol. 38,2 (2021): 1202-1211.

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Clinical Indications for Total Abdominal Hysterectomy among Women Seen in Dar es Salaam Regional Referral Hospitals, Tanzania: A Prospective, Observational Hospital-Based Study

Godfrey J Chale[1], Rashid M. Salim[2], Kelvin M Leshabari[1]
[1]Ultimate Family Healthcare Trust, Tanzania
[2]Kampala International University, Tanzania

Statement of the Problem: Total abdominal hysterectomy is among the commonest gynaecologic surgeries observed in Africa. However, there exists a gap in published data to support this hypothesis. Information on hysterectomies reported from sub-Saharan Africa reflects mostly obstetric indications. The purpose of this study was to assess and document clinical indications for total abdominal hysterectomy in Dar es Salaam hospitals.

Methodology & Theoretical Orientation: A prospective hospital-based study was conducted in Dar es Salaam, Tanzania from March-October 2017. Women attending the facilities with clinical conditions necessitating abdominal hysterectomies were the target population. Each woman was followed from the time of planning for surgery until at most 72-hours post-surgery or discharge from the wards whichever came first. Continuous variables were summarized using median (with corresponding inter-quartile range). Categorical variables were summarized using frequency (%). Data outputs were created using SAS version 9.4. Verbal informal consent was sought from each individual prior to inclusion to this study.

Findings: We recruited and prospectively followed-up 107 patients. Median age of participants was 42 (IQR: 37-47) years. Uterine leiomyoma (84.1%) was the leading indication for hysterectomy. Only about a third (30.8%) of followed-up women had provisional diagnoses at the time of surgery. None of the study participants reported receipt for confirmatory histological findings of her uterus up to the hospital discharge time post-surgery.

Conclusion & Significance: Uterine leiomyoma was the leading indications for total abdominal hysterectomy in Dar es Salaam, Tanzania. No histological findings to back up diagnoses were given back to patients at the time of the study.

Recommendations: Regular clinical audits on surgical interventions are warranted in this setting.

References

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3. Wright JD, Chen L, Burke WM et al (2016) Trends in use and outcomes of women undergoing hysterectomy with electric power morcellation. JAMA 316:877
4. Multinu F, Casarin J, Tortorella L, Huang Y, Weaver A, Angioni S, Melis GB, Mariani A, Stewart EA, Laughlin-Tommaso SK (2019) Incidence of sarcoma in patients undergoing hysterectomy for benign indications: a population-based study. Am J Obstet Gynecol 220(2):179.e1–179.e10