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Meeting Report

Closing the gap for cervical cancer research in Vietnam: current perspectives and future opportunities: a report from the 5th Gynecologic Cancer InterGroup (GCIG) Cervical Cancer Research Network (CCRN) Education Symposium

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PURPOSE

1. Review the incidence and the prevalence rates, and the current management strategies being used to reduce the cervical cancer in Vietnam.
2. Review the current state of research capabilities in Vietnam regards to the infrastructure for radiation therapy (RT), surgical procedures, and systemic therapy for treating cervical cancer.
3. Identifying the gaps in the infrastructure for cervical cancer treatment and research in Vietnam and discussing potential solutions for addressing these gaps.
4. Discuss the perspectives of government involvement including regulation consideration on cervical cancer research and treatment in Vietnam.
5. Discuss the potential opportunities for improving cervical cancer research and treatment in Vietnam, including education, collaborations, and funding sources.

Author Contributions

Conceptualization: T.D.S.P., N.R., P.N.T.H., B.K., C.B.A.; Project administration: T.D.S.P., N.R., P.M., P.N.T.H., B.K., C.B.A.; Writing-original draft: P.N.T.H.; Writing-review & editing: P.N.T.H., T.Q.T., N.N.P.T., N.H.T., T.L.D.N., P.V.C., B.K., C.B.A., P.M., S.D.H., N.R., T.D.S.P.

INTRODUCTION

Cervical cancer is the leading cause of cancer-related deaths in Vietnam. In 2020, the incidence rate of cervical cancer was 20.51 cases per 100,000 women, leading to 2,223 deaths in Vietnam [1]. Although several countries have successfully implemented nationwide screening programs resulting in a decrease in cervical cancer burden, Vietnam has yet to implement a national screening program. Consequently, Vietnamese women have limited opportunities to undergo screening tests due to poverty and lack of knowledge. As a result, patients often present at hospitals with advanced-stage cancer. For example, at least 75% of the cervical cancer patients in Ho Chi Minh Oncology Hospital and Danang Oncology Hospital are at stage IIB or above. Approximately 13% of those who were diagnosed with cervical cancer present with stage IVB disease. This report aims to identify the current situation regarding cervical cancer treatment in Vietnam and provide strategies for reducing the gap between low- and middle-income countries and higher-income countries [2].

1. Cervical cancer treatment

Vietnam has a population of over 98 million people across 63 cities and provinces. Despite the big population, there are only 15 dedicated oncology hospitals and centers. At present, there is not yet a formal oncology and radiotherapy specialist training program. Specialists have received their training abroad or on the job training.

National guidelines for the treatment of cervical cancer recommend that patients with early-stage cervical cancer should undergo surgery, while those with advanced stages should receive chemoradiation or chemotherapy [2]. However, the technique of sentinel lymph nodes dissection has yet to be implemented due to lack of training and surgical equipment. Additionally, although the Ministry of Health (MOH) has approved bevacizumab and immunotherapy for cervical cancer treatment, few patients are able to receive these treatments due to the high cost of these therapies.

2. Available resources for RT

Since most patients present with locally advanced disease, availability of RT and brachytherapy is an essential component of treatment options. The most recent survey of RT centers throughout Vietnam at the 5th Gynecologic Cancer InterGroup (GCIG) Cervical Cancer Research Network (CCRN) Educational Symposium showed that the number of linear accelerators ranged from 1 to 13, and brachytherapy units ranged from 0 to 4 in different cities and provinces in Vietnam. Ho Chi Minh Oncology Hospital had the highest number of the external beam RT and brachytherapy machines, treating over 2,600 patients annually (**Table 1**). Although one center

Table 1. Available resources for radiation therapy and clinical trials in 10 sites represented at the 5th Gynecologic Cancer InterGroup Cervical Cancer Research Network Educational Symposium [3]

Sites	No. of patients	No. of external beam radiation therapy machines	No. of brachytherapy units	No. of clinical trials on cervical cancer	No. of clinical trials on immunotherapy
K Hospital	1,500	6	3	3	0
Hanoi Oncology Hospital	512	2	1	1	15
Oncology Center – Bach Mai Hospital	100	2	1	0	0
Thai Nguyen Oncology Hospital	30	1	0	0	0
Quang Nam General Hospital	25	1	0	0	0
Danang Oncology Hospital	230	2	1	0	0
Can Tho Oncology Hospital	2	1	1	1	2
175 Military Hospital	40	2	1	0	0
Tu Du Hospital	215	0	0	4	0
Ho Chi Minh Oncology Hospital	2,627	13	4	5	5

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has recently introduced magnetic resonance imaging guided adaptive brachytherapy, and several more have started using computed tomography imaging for brachytherapy, the majority of centers and patients are treated with point-A based standardized brachytherapy plans.

However, due to the high incidence of advanced cervical cancer cases and the limited availability of RT equipment, patients often have to wait for 4 to 8 weeks before receiving treatment, and brachytherapy is mainly point-A based.

During the workshop, project ACTIVE was presented in which a radiation equipment vendor and an NGO collaborate to facilitate expansion of radiotherapy equipment and training.

3. Cervical cancer clinical trials in Vietnam

From the reports of representatives from cancer centers who attended the 5th GCIG CCRN Educational Symposium, most cancer hospitals and centers in Vietnam have not yet established clinical trial teams, with only a few hospitals in the North and South having such teams. However, the number of the clinical trials for cervical cancer in Vietnam remains low, ranging from 1 to 5. Regarding translational research capabilities, many advanced molecular biology and immunohistochemistry techniques have not yet been approved by the MOH in Vietnam for use in patient stratification for biomarker-driven early phase clinical trials [3].

CLOSING THE GAP FOR CERVICAL CANCER THERAPY IN VIETNAM

It is clear that many regions in Vietnam lack adequate infrastructure and the vast majority of patients presents at advanced stages,, resulting in a high mortality rate from cervical cancer. To address these challenges, key steps such as the implementation of a national cervical cancer screening and human papillomavirus vaccination program, more funding for RT equipment, national insurance coverage for targeted therapy should be prioritized. Importantly, further expansion of research capabilities, activation of own dedicated research programs, as well as faster regulatory approval for clinical trials will be required and contribute to further improvement in outcomes of Vietnamese women with cervical cancer. These initiatives will require the support from the Vietnamese government so that more funds from the national budget can be allocated to addressing these important issues.

The regulation of pharmaceuticals in Vietnam, particularly immunotherapy have historically been driven by the need to make essential medicines accessible to patients. However, the number of the patients receiving new drugs is limited due to high costs and low insurance coverage. High cost of new targeted therapies is a concern for low- and middle-income countries (LMIC), which is especially valid in the context of the burden of cervical cancer. Additionally, molecular tests, including immunohistochemical assays, have not yet been approved by the MOH. Therefore, improving the regulations on targeted therapy and clinical trials could help to enhance the current situation in Vietnam.

THE PROCESS FOR THE APPROVAL OF CLINICAL TRIALS IN VIETNAM

Vietnam's MOH is the regulatory authority responsible for clinical trial approvals, registration,

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oversight, and inspections. The MOH grants permission for clinical trials to be conducted in Vietnam. As per the ClinDrugTrial and PharmLaw-VNM, the scope of the MOH's assessment includes all clinical trials (phases I–IV) for the following [4,5]:

- Drugs that contain a new active ingredient, or products with a new combination of marketed ingredients
- Newly developed biologics or biologics with a new combination of marketed ingredients
- Newly developed vaccines that are manufactured and used for the first time in Vietnam
- Drugs, biologics, and vaccines which have been legally marketed for a period of less than 5 years in the country of origin (or a country of reference if provided for under international treaties to which Vietnam is a signatory)
- Drugs, biologics, and vaccines for which a clinical trial has been conducted, but have not met the MOH's or internationally recognized good clinical practice (GCP) requirements

The MOH's Administration of Science, Technology and Training (ASTT) is responsible for managing the clinical trial review process and registering contract research organizations that support clinical studies and provide other research services. Per the ClinDrugTrialGCP, research institutions must submit dossiers requesting clinical drug trial approval to the ASTT. The ASTT checks the validity of the dossier, and if it is incomplete, the ASTT will provide a written notice and specific instructions for the institution to supplement the dossier. The institution is responsible for coordinating with the ASTT to complete the dossier within a maximum of 60 days from the date of receipt of the written notice. Past this time limit, the research approval procedure must be repeated from the beginning.

The National Ethics Committee in Biomedical Research (NECBR), is responsible for approving the research proposal. The ClinDrugTrialGCP states that following receipt of a complete and valid dossier, the MOH will hold a meeting of the NECBR. After receiving the NECBR's evaluation report, the ASTT will synthesize and complete the dossier, then submit it to the Minister of Health for approval if the protocol meets the requirements. If the proposal is not approved or needs correction, the ASTT will notify the institution in writing and clearly state the reason. If the proposal needs to be modified, the institution is responsible for coordinating with the ASTT to complete the dossier in up to 90 days from the date of receipt of the written notice. Past this time limit, the protocol approval procedure must be repeated from the beginning.

OPPORTUNITIES IN THE FUTURE

In an effort to explore how we can close the gap on cervical cancer treatment and outcomes for women in Vietnam, the 5th GCIG CCRN Educational Symposium, with the central theme of "Improving outcomes for women with cervical cancer in low- and middle-income countries" was organized by the –GCIG-CCRN in collaboration with Da Nang Oncology Hospital on February 25th–26th, 2023 in Da Nang. Sessions at the symposium included topics such as education & mentorship for gynecologic cancer research and training; expansion of research studies to LMICs, workshops on state of the art radiotherapy techniques, and a comprehensive review on the latest data on surgery, immunotherapy and systemic therapy in cervical cancer. Updates on ongoing and completed GCIG CCRN clinical trials including SHAPE, SENTICOL AND CONTESSA, in which participants could potentially participate, were also presented.

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The symposium ended successfully with the hope that physicians and researchers in the country will be able to continue to receive further mentorship and training with the international faculty members and participate in more clinical trials in surgery, radiation therapy, immunotherapy and other novel therapeutic agents in the near future (**Fig. 1**). Furthermore, initiatives for research projects aimed at better understanding specific needs for Vietnam women, and implementation research was discussed as opportunities to enhance the overall research infrastructure and program.

Fig. 1. Some of images from the 5th GCIG CCRN Educational Symposium. (A) Dr. David Tan introduced GCIG CCRN. (B) Dr. Remi Nout training for Vietnam radiation oncologists. (C) One hundred twenty-three delegates throughout Vietnam. (D) National and international speakers. (E) In-person and virtual platform. (F) Dr. Suh introduced *Journal of Gynecologic Oncology* to audiences. (G) A very successful GCIG CCRN Educational Symposium.
CCRN, Cervical Cancer Research Network; GCIG, Gynecologic Cancer InterGroup.

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SUMMARY

The symposium report identified significant challenges facing cervical cancer treatment in Vietnam, such as insufficient infrastructure for prevention and treatment, clinical trials and research studies. In order to bridge the gap between Vietnam and other high-income countries, further support from the national government in terms of regulatory consideration and equipment investment, as well as global cooperation to improve education and research capabilities in cervical cancer is crucial. Moreover, institutions must publish more data on their capacity to deliver standard of care treatment for patients in Vietnam in order for the relevant authorities to better understand the specific challenges they face in delivering optimal cancer care for their patients.

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