Journal of Interdisciplinary Histopathology, 2022
VOL 10, NO. 7, PAGE 01-02

COMMENTARY

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The Need for Quality Control in Cervical Pap Smear Reporting

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ARTICLE HISTORY
Received: 01-Jul-2022, Manuscript No. EJMJIH-22-68228;
Editor assigned: 04-Jul-2022, PreQC No. EJMJIH-22-68228 (PQ);
Reviewed: 18-Jul-2022, QC No. EJMJIH-22-68228;
Revised: 25-Jul-2022, Manuscript No. EJMJIH-22-68228 (R);
Published: 02-Aug-2022

Description

Cervical cancer has a well-known etiopathogenesis and there are simple screening methods available for early detection. Despite this, cervical cancers rank the fourth most common cancer in women globally [1]. The prevalence is much higher in Asia-Pacific countries with one third contribution from India and China [2]. The non-implementation of HPV vaccination to vulnerable population, the fear and stigma attached to HPV vaccination, lack of community based screening and inaccessibility to health care set up for a larger population of women are the short comings that has led to the increasing rates of cervical cancer in developing countries [3]. Several measures are being taken to achieve the goal of eliminating cervical cancer, which is feasible only with high rates of HPV vaccination and commissioning population based screening programmes. Methods to administer HPV self-sampling are a promising effective screening for cervical cancer and can overcome the current challenges faced by the health care system. This is also recommended by the WHO especially in countries where HPV testing is not available as a national screening programme [1].

The global strategy for cervical cancer elimination was adopted by WHO in the year 2020. The key pillars for attaining this target were set as "90-70-90 targets" and each country should meet these targets by 2030. By "90-70-90 targets", the WHO set guidelines to achieve full vaccination in 90% of girls by the age of 15 Years, screening using high-performance test by the age of 35 Years and again by the age of 45 Years in 70% of women, while 90% women with per-invasive cancer getting treatment and those with invasive cancer getting proper management [4].

While devising methods to implement the above, it is equally important to have good quality reports to identify the screened population. It is a well-known fact that the cytopathology reports play an important role in identifying early precursor lesions deciding patient management. The scientific way to know the quality of cytopathology reporting is by implementing quality control measures in cytopathology, which will not only reflect the performance of the laboratory, but will also provide scope for further improvement in different aspects of quality.

As there are no established guidelines for monitoring quality control, the Clinical Laboratory Improvements Amendments of 1988 (CLIA-88) mandated certain quality control practices to reduce the laboratory errors. This included (i) a minimum of 10% of negative cases to be re-screened, including random and high risk cases, (ii) 5-year retrospective review of cases diagnosed as HSIL or higher (iii) Cyto-Histological Correlation (CHC). The 10% rescreen was largely applicable to those labs where the pap smears are screened by cytotechnologist and must be done prospectively. In view of several drawbacks, alternatives to 10% rescreen, like 100% rescreen, rapid rescreening, and computer assisted rescreening and sharing cases amongst laboratories were suggested. However, in most laboratories a certified pathologist reports the Pap smears, lowering the need for rescreening as a quality control procedure. The 5 year retrospective screening was too intense and the likelihood of detecting abnormalities was very low. The CAP in lines with CLIA has agreed upon CHC as a useful and applicable quality metrics for cervical cytopathology. Several guidelines for the process of CHC were suggested by the CAP [5], which is modifiable as per the prevailing laboratory practices in the country [6]. The College of American Pathologist Gynecologic Cytopathology Quality consensus Conference working group 4 laid down several consensus statements on quality improvement in CHC for gynecological cytopathology with additional quality practices to improve CHC [6].

ASC/SIL ratio is a widely practised method of cytopathology quality assessment in most laboratories [7]. Reporting "atypical squamous cells" does not imply the

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nature of atypia as to reactive or neoplastic and therefore implies uncertainty in diagnosis and management. The Bethesda suggested a benchmark to curtail the over use of ASCUS and suggested that the ratio should not be more than 3:1 [8].

Using these quality metrics along with Positive Predictive Value (PPV) of Pap smear, we conducted a 6 year retrospective study, to evaluate the quality of cytopathology reports using three quality metrics, i.e. ASC/SIL ratio, PPV of pap smears and CHC [9]. The ASC/SIL ratio was 1:2.6 which was well within the acceptable limits. The PPV of pap smears was 96.4%, which falls within reported range of PPV in large series {between 71%-94%} [10]. The cytohistological correlation was maximum (100%) in ASC-H and SCCs and lowest (93.6%) for HSIL with other lesions falling in between. An analysis of the discordant results showed sampling and interpretative errors leading to discordance.

The three quality metrics used in the study were feasible and easily adoptable by laboratory and are effective tools to assess the quality of cytopathology reporting in a laboratory. Since there are no stringent metrics given by the regulatory authorities, the CAP has suggested that every lab should define its own quality metrics and should lay down guidelines regarding the nature, periodicity, correlation interval with defining of discrepancies, calculation of PPV, notification to the physician, policy on review of discordant cases. This will help to improve the quality of functioning of a cytopathology laboratory and will work towards achieving cervical cancer elimination strategies of WHO by 2030.

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