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Role of Biomarkers in Cancer Drug Development: A Mini Review

Article by Sayanth Raj1, Imran Shareef Syed1, Niharika Anand1, Jessica Dasari1, Rozmina Banu1
1MD, Texila American University - College of Medicine, Guyana, South America

Abstract

Biomarkers, or biological markers, are defined in various ways. Some define it as 'a biologic feature that can be used to measure the presence or progress of disease or the effects of treatment. One goal of biomarker usage in clinical research is to expedite the drug development process to produce drug therapies as efficiently as possible, while maintaining the safety profile. Biomarkers have been used for decades, from monitoring blood pressure to lipid levels. Tumor biomarkers represent an effective tool for tumor diagnosis, treatment, prognosis, and therapeutic monitoring. Ideally, the use of biomarkers in early trials would help predict the likelihood of success or failure of a drug in efficacy trials. Biomarkers can predict drug efficacy more quickly than conventional clinical end points; they hold the potential to substantially accelerate product development in certain disease. This review is mainly focused on the role biomarkers in cancer drug development process and the literature was collected from articles published in PUBMED, Medline, and the Cochrane Database of Systemic Reviews.

Keywords: Biomarkers; Clinical trials; Drug Development; Cancer.

Introduction

Biomarker is a substance/structure/process that can be measured in the body or its products and influence or predict the incidence of outcome or disease. Apart from the fact that biomarkers are very useful tool in accessing the progression of the disease and determine the treatment of success, there has been a trend in ongoing interest of role of biomarkers in preparation and testing the safety and efficacy of anticancer drug. Chemotherapy development has started since 1940s, where antifolate and nitrogen mustard were used for first time[1] since then cancer drug development has transformed and now, we have drugs which targets the specific molecular targets (receptors) which are as a result of mutation that caused cancer. The slow progression of anticancer drug development and high rates of failure is believed to be lack of predictive animal models which reflects the human experience. [2] According to a systematic review the use of biomarkers in phase I trials has increased over the period from 1991 to 2002 [2] and study has also shown that the biomarkers are used to limited extent for dose selection in phase II clinical trials.

Biomarkers in clinical trials

Clinical trials conducted among the patients with Gastrointestinal Stromal Tumors (GIST), a rare form of soft tumor to evaluate role of Imatinib in Patient survival rate and safety and efficacy of drug has shown promising results.[3] In another research the role of lapatinib was accessed in patients suffering from heavily treated advanced malignancies showing overexpression of tumor markers ErB1 and /ErB2 and results showed lapatinib exhibited preliminary of biological and clinical activities. A study shows synergistic effect of ZH1 when combined with gemcitabine, both combined has strong anticancer activity as they both enhances the apoptotic pathway in the body which is often disturbed in cancer.[4] Potential antitumor activities of glaucocalyxin A (GLA), an ent-kaurene diterpenoid isolated from Rabdosia japonica were accessed using gas chromatography–mass spectrometry(GC/MS) and liquid chromatography–mass spectrometry(LC/MS) based metabolic profiling and has shown positive results.[5] Lower class of small molecular therapeutics like histone deacetylase inhibitors (HDACi) are now approved by food and drug administration (FDA) as an anticancer agent. These drugs act as transcriptional repressors by removing acetyl group from histones. Hence combination of HDACi and anticancer drugs has shown promising results.[6]
Proteomic technologies are extensively used in anticancer drug discovery and development.[7] Anthoporaanjunae is an antitumor peptide obtained from sea anemone, in a recent study this antipeptide has been shown to cause an inhibitory effect on prostate cancer DU-145 cells proliferation using methylthiazolyldiphenyl-tetrazolium bromide assay. This peptide increases the expression of apoptotic caspases and inhibits BCL-2 which is an antiapoptotic agent already found in our body and frequently over expressed in cancer conditions. [8] Advances in fields of inorganic chemistry have opened the pathways to new and effective anticancer regimen. Certain synthetic complexes have anticancer activity shown in a recent study. Where complex iridium upon irradiation with white light shows highly cytotoxic against BEL 7402 cells. The mechanism being it inhibits cell growth by reactive oxygen species (ROS) mediated mitochondrial destruction and targeting tubular pathways. The researchers are in progress and it is believed that this complex will be used to develop multi-cancer drugs. [9]

Phase III trials with ipilimumab showed an improved survival in patients with metastatic melanoma. [10] Numerous clinical trials are having taken place in past few years and results are positive in most cases. Moreover, the advanced radiologic imaging techniques are now extensively used and are accurate to detect the cancer at very early stage and leads to low cancer related deaths.[11] however researches are still going on. As deduced from above few researches mentioned it is understood that tumor markers play an inevitable role in diagnosis, treatment, prediction of treatment outcome. Some of the identified biomarkers played an important role in drug development are described in Table – 1.

Biomarkers in cancer

The use of biomarkers in clinical research has paved way for the discovery of the progression and in turn, the treatment of various diseases. For example, oncology is one field wherein the role of biomarkers has created a major impact. Despite the recent decline in the incidence of cancer, long-term mortality rates remain unchanged. One of the most important factors in the survival of cancer is detection at an early stage. Clinical assays that detect the early events of cancer offer an opportunity to intervene and prevent cancer progression. Biomarkers are important molecular signatures of the phenotype of a cell that aid in early cancer detection and risk assessment. [12] Although tumor markers greatly improve diagnosis, the invasive, unpleasant, and inconvenient nature of current diagnostic procedures limits their application. [13] Hence, there is a great need for the identification of non-invasive biomarkers for the early detection of tumors. Recent studies have found that that serum and plasma contain many stable miRNAs derived from various tissues/organs, and that the expression profile of these miRNAs shows great promise as a novel non-invasive biomarker for diagnosis of cancer and other diseases. [14] Another study showed the use of biomarkers in distinguishing between colon and ovarian cancer. These types of cancer maybe often difficult to differentiate in ovarian masses, in peritoneal carcinomatosis, and in metastases to distant lymph nodes. Misdiagnosis in this context may result in delayed identification of the primary lesion or misdirected clinical procedures. It may also lead to inappropriate therapy because metastatic colon cancer is generally treated with 5-FU, whereas ovarian cancer is most often treated with paclitaxel and a platinum agent [15, 16]. This study indicates that villin and perhaps moesin should be strongly considered for clinical use in distinguishing colon and ovarian carcinomas. [17]

Recent advances in biomarkers research had provided a reliable, non-invasive method for the early detection of cancer, and thereby to improve the chances for successful therapy and preclude the use of an invasive biopsy. While screening the prostate cancer, Prostate Specific antigen (PSA) is one of the most important biomarkers but it leads to over-diagnosis and over-treatment because of the less specificity while screening. According to Niels Asger Jakobsen et al. there are lot of novel biomarkers came into the picture for screening the prostate cancer but still they are not put forward to clinical practices instead they are using PSA as a biomarker. So, to minimize this bias usage of the novel biomarkers like four-kallikrein panel, fPSA and PCA3 into the Prostate Cancer Prevention Trial Prostate Cancer Risk Calculator (PCPTrc) and the European Randomized Study of Screening for Prostate Cancer (ERSPC) multivariable prediction model can help clinicians to diagnose and treat precisely. [18]In 2011 Pritchard et al. exclaimed that circulating, cell-free micro RNAs (miRNAs) is
one of the important biomarkers for the screening of cancers particularly leukemias, lymphomas and tumors which shows secondary effect on blood cells. [19] But some studies prove that there are different types of miRNAs which can be used as biomarkers for various cancer types including detection of breast cancer in the early stages. Detection of breast cancer in early stages is very important which can be attained by the level of serum miRNAs. [19] Lack of efficacy and safety of a drug which is developed and manufactured without using any clinical biomarker is the major drawback in clinical trials therefore FDA has launched the Critical Path Initiative to develop drugs using biomarkers for proper diagnosis and treatment in cancer therapy. Biomarkers can be used in different phases of drug discovery and development they are Target identification and validation, Lead identification and optimization, Preclinical development, Early-stage clinical development and Late-stage clinical development. There are different kinds of biomarkers namely

1. Target engagement: a drug which is been bound by fraction of target binding sites
2. Pharmacodynamics: Drug effects on the human body to assess whether the downstream pathway or biological process regulated by a drug target is perturbed upon drug administration.
3. Disease activity: Effects of a drug on a disease, which occur late in the pathophysiologic cascade and are linked to clinical benefit.
4. Surrogate endpoint: Substitution for a clinical endpoint and prediction of clinical benefit with certainty.

Safety biomarkers are one of the important biomarkers, but they are still in phase III clinical trials. [21] Mutations that occur in some of the biochemical substances present in human body such as BRAF V600E, anaplastic lymphoma kinase (AKL), and BCR-ABL translocation product may act as clinical biomarkers in melanoma, lung cancer and chronic myelogenous leukemia (CML) respectively, these biomarkers are selected for molecular anticancer therapy. Some of the identified biomarkers and their related to anticancer along with its mechanism of action (MOA) of drugs that are provided in the table - 2. To avoid usage of non-reactive and toxic drugs for cancer therapy it’s better to know about the relative biomarker to find key molecular pathways for targeting. Recently, some of the antibodies are used for the treatment of cancer by targeting Fc region to trigger immune response with the help of T-cell activation. For example, ertumaxomab is a rat-murine hybrid monoclonal antibody tested and confirmed in the phase I and phase II clinical trials that it is used for breast cancer therapy in those patients showing HER2 positive. [22]

There is certain type of drugs which lead to tissue damage and increase the level of novel urinary biomarkers in the body. For example, vancomycin is an antibiotic used for the treatment of acute kidney injury (AKI), but toxicity of this drug due to high dose and increased treatment duration may lead to histopathological damage and release of novel urinary biomarkers these studies are done on rat. [22] From above, it is clear, that certain tumor biomarkers are making a major contribution to cancer detection and patient management. Indeed, in some situations, biomarkers can be used as the only available criterion for clinical decision making.

In the future, the trend will be to simultaneously measure multiple biomarkers with technologies such as microarray, multiplex PCR, multit gene sequencing and eventually whole genome analysis. The use of multiple markers can potentially capture more fully, intra-tumor heterogeneity and provide more comprehensive clinical information and which helps to produce new anti-cancer drugs in to the market.
Table 1. Biomarker/Surrogate endpoints that have aided drug development

<table>
<thead>
<tr>
<th>Biomarker/Surrogate Endpoint</th>
<th>Type of Drug</th>
<th>Clinical Endpoint</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood pressure</td>
<td>Antihypertensives</td>
<td>Stroke, atherosclerosis, heart failure</td>
</tr>
<tr>
<td>Cholesterol</td>
<td>LDL-lowering statins</td>
<td>Coronary artery disease, heart attacks</td>
</tr>
<tr>
<td>Viral RNA</td>
<td>Antiretroviral agents</td>
<td>Survival, decrease in infections</td>
</tr>
<tr>
<td>HbA1C, glucose</td>
<td>Antidiabetic agents</td>
<td>Diabetic neuropathy</td>
</tr>
<tr>
<td>CD4+ T cells</td>
<td>Antiretroviral agents, Cytokines</td>
<td>Sustained reduction in viral RNA</td>
</tr>
<tr>
<td>Intraocular pressure</td>
<td>Antiglaucoma agents</td>
<td>Preservation of peripheral vision</td>
</tr>
<tr>
<td>Bone mineral density (BMD)</td>
<td>Antiosteoporotic agents</td>
<td>Fracture rate</td>
</tr>
<tr>
<td>MRI scans</td>
<td>Agents for treatment of MS</td>
<td>Decrease in rate of progression disease</td>
</tr>
<tr>
<td>CT scans for tumor size</td>
<td>Anticancer agents</td>
<td>Survival</td>
</tr>
</tbody>
</table>

Table 2. Table showing the biomarker identified in different types of cancers and drugs that has been used along with its action

<table>
<thead>
<tr>
<th>Cancer Type</th>
<th>Biomarker identified</th>
<th>Related Drug Used</th>
<th>Drug Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lung cancer</td>
<td>ALK</td>
<td>Ceritinib</td>
<td>Tyrosine kinase inhibitor of ALK</td>
</tr>
<tr>
<td>Colorectal cancer</td>
<td>EGFR</td>
<td>Panitumumab</td>
<td>Humanized monoclonal antibody directed against EGFR</td>
</tr>
<tr>
<td>Breast cancer</td>
<td>HER2</td>
<td>Lapatinib</td>
<td>Reversible tyrosine kinase inhibitor of EGFR, HER2</td>
</tr>
</tbody>
</table>

References
[21]. Xuemei Zhao, Vijay Modur, Leonidas N. Carayannopoulos, Omar F. Laterza Clinical Chemistry Nov 2015, 61 (11) 1343-1353;
Users’ Perception about Library Service Quality at Texila American University, Guyana, South America: A LibQUAL+™ Study

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E-mail: shyam.r@tau.edu.gy

Abstract

This article is designed to measure the library service quality on library usage and user satisfaction. The LibQUAL+™ was used in this study, which is a valid tool and implemented across the world to measure the users’ satisfaction in academic, special and public libraries. The data was collected from the students through online questionnaire was uploaded to Learning Management System (LMS) portal of Texila American University in the month of January and November, 2018. The data was analyzed through SPSS. The findings indicate that library service quality has a significant positive effect on library usage and direct significant effect on user satisfaction services.

Keywords: LibQUAL+™, library service quality, library usage, user’s perception and user’s satisfaction.

Introduction

Library is a service-oriented and user-centered academic learning environment; library assessment is a required process to measure a library’s performance quality and service improvement while supporting the missions and the needs of an academic institution of higher education.

Matthews et al, indicated that ranges and scopes of an academic library assessment have been expanded to include student learning outcomes6 (i.e. student’s achievements, experiences, and retention), teaching effectiveness, research environment, library as a place, and impacts on a college or a university’s reputation.

Measuring users’ perception about service quality in libraries through LibQUAL+™ approach. LibQUAL+™ similar to ServQual are designed8, but it is more focused and pertinent to Libraries, designed on the basis of the “Gap Theory of Service Quality8.

LibQUAL+™ give library users a chance to tell where services need improvement so that they can respond to and better manage their expectations. Libraries can develop services that better meet users’ expectations by comparing library’s data with that of peer institutions and examining the practices of those libraries that are evaluated highly by their users. It allows seeing relationship to the other academic libraries. It is a starting point to identify best practices improving library services with the help of LibQUAL+™. In this article, LibQUAL+™ instrument was used to assess the level of service provided at Texila American University, Guyana, South America on “Effect of Service, Information Control and Library as Place dimension.

Objectives of the study

The objectives of the study are:
1. To find out the differences between level of services amongst the students.
2. To determine students’ satisfaction and comparative study about the library services.
3. To propose solutions for improving the library’s level of service.

Methodology

Students of Texila American University have actively participated in the LibQUAL™ survey. The LibQUAL™ questionnaire was uploaded in Learning Management System (LMS) portal on random sampling technique to obtain student satisfaction/perception on library services. The data was analyzed by using statistical Package for Social Sciences (SPSS) 16 version.
Results

The library service satisfaction response was received from students (Table – 1) of Texila American University, Guyana, South America through TAU Learning Management System Portal.

<table>
<thead>
<tr>
<th>S.No.</th>
<th>Category</th>
<th>January, 2018</th>
<th>November, 2018</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Male students</td>
<td>24</td>
<td>41</td>
<td>65</td>
</tr>
<tr>
<td>2.</td>
<td>Female students</td>
<td>48</td>
<td>63</td>
<td>111</td>
</tr>
</tbody>
</table>

The LibQUAL™ survey conducted in the months of January and November, 2018. The comparative data analysis shows that, overall 76% of the users were satisfied in the month of January, 2018 and compare with November, 2018 shows that, 83% of the students were satisfied with our Library Services on each individual item. The results show in the following Table – 2.

<table>
<thead>
<tr>
<th>S.No.</th>
<th>Questions</th>
<th>January, 2018</th>
<th>October, 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Affect of Service Dimension</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Employee who instill confidence in users</td>
<td>72%</td>
<td>80%</td>
</tr>
<tr>
<td>2</td>
<td>Giving users individual attention</td>
<td>76%</td>
<td>85%</td>
</tr>
<tr>
<td>3</td>
<td>Employees who are consistently courteous</td>
<td>74%</td>
<td>82%</td>
</tr>
<tr>
<td>4</td>
<td>Readiness to respond to users’ questions</td>
<td>79%</td>
<td>84%</td>
</tr>
<tr>
<td>5</td>
<td>Employees who have the knowledge to answer user questions</td>
<td>77%</td>
<td>86%</td>
</tr>
<tr>
<td>6</td>
<td>Employees who deal with users in a caring fashion</td>
<td>75%</td>
<td>83%</td>
</tr>
<tr>
<td>7</td>
<td>Employees who understand the needs of their users</td>
<td>74%</td>
<td>83%</td>
</tr>
<tr>
<td>8</td>
<td>Willingness to help users</td>
<td>80%</td>
<td>85%</td>
</tr>
<tr>
<td>9</td>
<td>Dependability in handling users’ service problems</td>
<td>74%</td>
<td>81%</td>
</tr>
<tr>
<td></td>
<td>Library as Place Dimension</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Library space that inspires study and learning</td>
<td>78%</td>
<td>87%</td>
</tr>
<tr>
<td>11</td>
<td>Quiet space for individual activities</td>
<td>76%</td>
<td>87%</td>
</tr>
<tr>
<td>12</td>
<td>A comfortable and inviting location</td>
<td>80%</td>
<td>83%</td>
</tr>
<tr>
<td>13</td>
<td>A gateway for study, learning, or research</td>
<td>77%</td>
<td>83%</td>
</tr>
<tr>
<td>14</td>
<td>Community space for group learning and group study</td>
<td>73%</td>
<td>80%</td>
</tr>
<tr>
<td></td>
<td>Access to Information Control Dimension</td>
<td></td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>How often do you use resources on library premises?</td>
<td>77%</td>
<td>79%</td>
</tr>
<tr>
<td>16</td>
<td>Making electronic resources accessible from my home or campus</td>
<td></td>
<td>82%</td>
</tr>
<tr>
<td>17</td>
<td>The printed library materials I need for my work</td>
<td>I did not include these questions in the month of January, 2018</td>
<td>82%</td>
</tr>
<tr>
<td>18</td>
<td>The electronic information resources I need for my work</td>
<td></td>
<td>83%</td>
</tr>
<tr>
<td>19</td>
<td>Easy-to-use access tools that allow me to find things on my own</td>
<td></td>
<td>83%</td>
</tr>
<tr>
<td>20</td>
<td>Making information easily accessible for independent use</td>
<td></td>
<td>82%</td>
</tr>
<tr>
<td>Q.No</td>
<td>Questions</td>
<td>Satisfied</td>
<td></td>
</tr>
<tr>
<td>------</td>
<td>---------------------------------------------------------------------------</td>
<td>-----------</td>
<td></td>
</tr>
<tr>
<td>21</td>
<td>A Library Homepage enabling me to locate information on my own</td>
<td>77%</td>
<td></td>
</tr>
<tr>
<td>22</td>
<td>A modern equipment that lets me easily access needed information</td>
<td>80%</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>TOTAL USER SATISFACTION (Average)</strong></td>
<td><strong>76%</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>83%</strong></td>
<td></td>
</tr>
</tbody>
</table>

From the above table, with reference to Q. No.1 “Employee who instill confidence in users”, 72% were satisfied in the month of January, 2018 and there is a tremendous improvement by 80% in the month of October, 2018.

With regard to the Q.No.2 “Giving users’ individual attention” and Q.No.11 “Quiet space for individual activities”, the respondents were shows as 76% were satisfied on these items and 85% and 87% were satisfied with our services respectively.

With respective to the Q.Nos.3. “Employees who are consistently courteous”, 7. “Employees who understands the needs of their users” and 9. “Dependability in handling users’ problems”, it is observed that, 74% were satisfied on all these items and 82%, 83% and 81% were satisfied with our services.

From the above table on Q.No.4, “Readiness to respond to users’ questions” it shows that, 70% were satisfied in the month of January, 2018 and compare with October, 2018 is 84%. It shows that, library staff is able to respond to their queries.

It is observed on Q.No.5 “Employees who have the knowledge to answer user questions” and Q.No.13 “A gateway for study, learning, or research”, it shows that 77% were satisfied on these items in January, 2018 and compare with November, 2018 is 86% and 83% respectively.

With reference to Q.No.6 “Employees who deal with users in a caring fashion”, it shows that 75% and 83% were satisfied on these items in January, 2018 and November, 2018 respectively.

With respect to Q.No.8 “Willingness to help users” and Q.No.12 “A comfortable and inviting location”, 80% users express their staff will help them and Library is an inviting premise by 80% on these two items and 85% and 83% respectively in November, 2018.

With regard to Q.No.10 “Library space that inspires study and learning”, the users were felt that, 78% were satisfied with the library space in January, 2018 and 87% were expressed that they were satisfied with the Library space will inspires for the study.

As regards to the Q.No.14 “Community space for group learning and group study” 73% and 80% users were Community space for group learning and group study in January, 2018 and November, 2018 respectively. It means, Library space is encouraging the users in learning and group study activities for their research and assignments.

With reference to the Q.No.15 “How often do you use resources on library premises? On Access to Information Dimension, it is observed that, 77% and 80% of the users were access to the resources on library premises in the months of January 2018 and November 2018 respectively.

With reference to the “Access to Information Dimension”, Q.No.16 “Making electronic resources accessible from my home or campus, Q.No.17 “The printed library materials I need for my work” and Q.no.18 “Making information easily accessible for independent use”, it shows that 82% of the respondents were satisfied on each item in the month of November, 2018.

From the above mentioned table, it is observed on Q.No.18 “The electronic information resources I need for my work” and Q.No.19 “Easy-to-use access tools that allow me to find things on my own”, 83% of the users were able to access the information on their own either from home or campus.

Similarly, the above table shows on Q.No.21 “A Library homepage enabling me to locate information on my own”, 77% were felt that, they can able to find whatever information required through Library Homepage. Still we will strive to improve the performance to reach more than 80% in the next LibQUAL™ survey.

With reference to Q.No.22 “modern equipment that lets me easily access needed information 80% of the users felt that, modern equipment’s are helpful to access the needed information.
Discussions and conclusion

Satisfaction of academic library users and their subsequent utilization of library resources are important for quality teaching, research and learning. Many libraries adopt a concept of service quality to better serve the user. Service quality; a term commonly defined in business and marketing from the customer perspective, has recently been a concern within library and information services sector. This is because the extent to which the library succeeds is dependent on the assessment made by the user as a judge of quality. Aware of the need to create a culture of continuous improvement, many academic libraries use LibQUAL+™ as a primary tool for fostering the culture of assessment and improvement.

Ruth M. Swan, (2004) in Florida A & M University Libraries conducted LibQUAL+™ survey. They measured on three dimensions of Library service: Effect of Service, Access to information Control and Library as Place. The total Respondents completed the LibQUAL+™ survey around 777 users. Respondents have very high expectations for library service quality. Mean values of minimal service quality for the group is 6.67 on a scale of 1-9. The desired mean is a mere 7.83, not far from the minimal. The perceived mean is 6.10, representing an overall service gap of 0.47. Respondents indicate that, they are satisfied with the willingness of staff to provide help, as needed, the functionality of the library web page, and the provision of a comfortable study environment. They also seek more funds for development of staff and improve customer relations and implement them in future period.

The current study analysis shows that, overall 76% of the users were satisfied in the month of January, 2018 and compare with November, 2018 shows that, 83% of the students were satisfied with our Library Services on each individual item. Which helped us to identify the issues requiring some extensive reorganization, but also it has provided us with a tool to measure how successful we are instituting changes to address to the user’s community. Out involvement in this program has communicated to our students, our commitment to involving them in our process of continuous service improvement.

Limitations

The study is confined to the students of Texila American University. Therefore, the results will be generalized only to this University. In this survey, the Online Questionnaire was served to the user community through LMS portal. Hence, the sample is not absolutely representation. Besides the time, the mindset of the students of the library might also have affected the data collection and data processing.

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https://www.researchgate.net/publication/241746268_The_LibQUAL_Challenge
Mullerian Duct Defect: Uterus Didelphys

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Abstract

This report is centered around a 20 years old patient with uterus didelphys who has successfully conceived, carried her pregnancy to term and delivered her twins by lower segment caesarean section as requested, without any significant complications. The best diagnostic modality will also be discussed and its importance in the next management step or surgical intervention.

Keywords: Mullerian duct defect; Congenital anomaly; Uterus Didelphys.

Introduction

Mullerian anomalies are one of the most alluring disorders seen in the obstetrician and gynecology department, especially ones that are on the rare end of the spectrum. The Mullerian ducts are the beginning of the female reproductive system which proliferates because the sex gene does not accommodate the production of testosterone. The ducts undergo fusion to form the uterine cavity with the two (2) fallopian tubes (one on each side), the cervix and the upper on third (1/3) of the vagina.

Uterine anomalies develop as the normal fusion of the ducts are hampered and agenesis, hypoplasia or both occurs. These uterine anomalies are classified into seven classifications (0-VI) for easy differentiation. Mullerian duct anomalies are often associated with renal and axial skeletal anomalies, and are usually discovered when patients are examined for another condition. Mullerian duct anomalies are usually asymptomatic and the normal sexual development of the female masks the internal problem with the uterus. This normal development and a wide variety of clinical presentation makes the diagnosis difficult; however once it is diagnosed there are several treatment options to provide the patient with that will be tailored to the specific defect. [1]

The incidence of the Mullerian duct defect depends on the authors and most reported an incidence of 0.1-3.5%.[3] In 2001, Grimbizis GF, Camus M et al obtained an incidence of 4.3% in the female population (complied 5 studies = 3000 women); 3-6% of women with infertility have an anomaly; 5-10% of women with recurrent abortions have an anomaly, mostly in 3rd trimester. Also, a Danish study of 622 women (20-74 years old), all of whom were examined with saline contrast sonohysterography, suggested the prevalence of Mullerian duct anomalies in the population to be 9.8%; the prevalence was particularly high in nulliparous women and in those with oligomenorrhea. Grimbizis GF, Camus M et al also had a prevalence of 4.3% in general population, 3.5% in infertile women and 13% with recurrent pregnancy loss.[2]

Uterus Didelphys is a class III Mullerian defect that comes about when the midline fusions of the ducts cease forming either complete or incomplete. This event causes the formation of two independent uterine cavities each with single horns and two cervixes. In 75% of cases, there can be a septate vagina giving the impression of two vaginas.[4] Women with Didelphys uterus are usually asymptomatic unless an obstruction is present, with symptoms being hematometocolpos, hematometra and hematosalpinx.

As mentioned above, there must be suspicion of renal anomalies; as there was a 20% chance recorded.[2] Some other parallel anomalies include bladder extrophy with or without vaginal hypoplasia, congenital vesico vaginal fistula with hypoplastic kidney and cervical agenesis.

Patients with this condition are not infertile and therefore are able to become pregnant. Twin pregnancy is quite rare. It is usually di-zygotic, di-chorionic and di-amniotic in independent uterine cavity. There are amazing cases where the second fetus is delivered after several days or weeks suggesting that the pregnancy can occur at separate times. However, lactation may only occur until the second fetus is delivered.
The obstetric outcome data of a patient with uterus didelphys is very minimal but can include unilateral placental abruption or unilateral preterm labor. [3] The management of delivery for these patients can be tricky and a choice between lower segment caesarean section (LSCS) or spontaneous vaginal delivery must be made.

Case report

A 20 years old G1P0 was first admitted on 20/02/2017 with a chief complaint of lower abdominal pain and lower back pain with frequent contractions and passing a big clot and slime. She is presenting with Dichorionic Dianniotic twin gestation at 32 weeks and 32+2 weeks (15+1 USG), preterm contractions, vaginal candidiasis and not in labor.

The patient was treated and had no complaints of contractions or any pain and so was discharged on 22/07/2017. On fetal non-stress test twin 1 was cephalic and twin 2 was breeched. She then presented to the hospital again on 10/08/2017 complaining of feeling a gush of greenish fluid in the washroom. On examination there were abundant vaginal candidacies and greenish cream secretions on speculum. The impression at admission was 20 years old G1P0 @35+5 (14+6 USG) Dichorionic Dianniotic twins with vaginal sepsis and preterm premature rupture of membranes was ruled out. The patient was treated and discharged the following day.

On 23/08/2017 the patient was at 37+6 gestation complaining of contractions every 20 minutes, greenish discharge and decreased fetal movement. On 24/09/2017 the patient was admitted for lower segment caesarean section (LSCS). She says that there is fetal movement and no show. On 25/09/2017 the LSCS was done and two intrauterine contraceptive devices were placed. Post LSCS the patient complained of lower abdominal pain and shortness of breath. On the 26/08/2017 the patient developed acute urinary retention secondary to inadequate pain management. The patient was treated and observed for the next few days. On the 29/08/2017 the Patient was discharged and told to follow up in clinic.

Discussion

Uterine Didelphys can present as an asymptomatic uterine anomaly as was shown in this case report. The patient had no abnormal menstrual pattern since menarche and there were no clinical manifestations of any abnormalities present within the patient. No manifestations were present because this patient had no obstruction (septum) in the vagina to cause any bleeding or interruption on coitus or cause any of the three: hematometrocolpos, hematometra or hematosalpinx to occur and the patient was not infertile.

Upon LSCS, a live baby boy was extracted at 38+1 weeks at 3100g and then a live baby girl was extracted at 38+1 weeks at 2800g. Also, both neonates had an APGAR score 9, 10, 10. The neonates had no complications and were both delivered at term. They had no restriction nor were they small for their gestational age. This proves that there is no restriction to the growth of the fetus by the hemi-uteri and as believed that the smaller cavity can contribute to preterm deliveries and small neonates were not applicable to this case.

To add to the LSCS events, the shape of the uterus was heart shaped which suggested a bi-cornate uterus, but on exploration the septum was noted and the double cervixes confirming uterus Didelphys. The misconception in the beginning of the case is possible because both mullerian defects have the same shape of uterus. The trans- abdominal ultrasonographies performed did not detect the uterine anomaly during pregnancy because of the thin septum between the two cavities. The MRI is mostly used to give a concrete diagnosis of a uterine anomaly and while at it, will also show any other associated renal anomalies that may be present. [6] Transvaginal sonography is also another great diagnostic tool for uterine anomalies. [6] The sensitivity and specificity of MRI is 100% while the endovaginal sonography(EVS) has a sensitivity of 100% and a specificity of 80%. [6] Both MRI and EVS have a 100% sensitivity and specificity in distinguishing those uterine anomalies that need repairs. These high values actually decrease the rate at which an invasive method of diagnosis is required.
When the diagnosis has been made and it is either complete or incomplete, a specific management will be considered for the patient. In this patient’s case the uterus was giving the patient no problems so there was no need for any form of management. However, it is advised that she should definitely be brought back to the institution to undergo an MRI scan or even a trans-abdominal ultrasonography so that any congenital anomaly can be ruled out since they are common in patients especially with uterus didelphys. Her daughter should also be screened for any mullerian duct anomalies as well as renal anomalies as it was noted to be a genetic relation by Golan A, et al in his research Congenital Anomalies of the Mullerian System.[7]

Conclusion

This study was done to help clinicians to better understand the reproductive, gestational and neonatal outcome in the case of uterus didelphys. Uterus didelphys is the rarest form of Mullerian duct defects and if it wasn’t for the surgeon’s inquisitive personality, we would have a common case of bicornate uterus instead of the rare defect of uterus didelphys.

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