Clinical File Management, Translational Research and Continuing Education for Cancer: a Single-unit Experience

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Research

Keywords: Cancer, Clinical file management, Biospecimen collection, Translational research, Lifestyle change, Doctor-patient relationship, Continuing education

Posted Date: December 23rd, 2020

DOI: <https://doi.org/10.21203/rs.3.rs-131864/v1>

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Abstract

Background: Cancer is considered clinically heterogeneous. Some cancers are indolent and localized, while others are aggressive and easily spread to other parts of the body with metastasis. Whether diagnosis methods or therapy selection has moved towards combination, personalization and diversity. Therefore, it is important to standardize clinical file management, biospecimen collection and translational research of cancer.

Methods: Data were retrieved from the Clinical Study Project on Cancer in XXXX, an ongoing longitudinal study including more than 1500 genitourinary cancer people.

Results: The standard clinical diagnosis, treatment and translational research workflow was built based on current medical administration technology, molecular research method and triangle coordination relationship among doctor, patient and researcher. Raised awareness of warning signs and improved healthy styles showed high-quality follow-up and clinical outcome. At last, the system helps research ability improvement based on the skills proficiency and achieve medicine-research-education integration.

Conclusion: Our analysis will help ensure patient health, enhance doctor-patient relationship, improve research efficiency and support continuing education. The goal of sustainable work participation in cancer survivors can be improved by the delivery of a personalised clinical management and education intervention. Furthermore, successful work outcomes often involve the cooperation of doctors, cancer survivors and clinical researchers.

Background

In clinical practice, cancer progression often owns to late-stage diagnosis, loss of follow-up, irregular treatment, pathological type and genetic factor. The deficiency of full-process managements on inquiry, diagnosis, treatment, file notes and follow-up usually lead to early cancer progression because of lack of prejudgment. Therefore, the establishment of standardization of clinical file management, biospecimen collection, educational Intervention, questionnaire inquiry and continuing training for clinical research coordinator is of great concern.

Research in standardization of clinical file management, biospecimen collection and translational research of cancer is often a challenge. These need professional bed-to-bench administration and experience based on training on doctor and researcher¹. Meanwhile, the communication between doctor, researcher and patient should be based on feedback data to assure smooth procedure. Whether it is a small survey, an interview or, on the other end of the spectrum, biospecimen collection, the challenges are real and can be seen in a multitude of ways.

The focus of this paper is to provide a standard process of clinical administration and study focused on clinical file management, biospecimen collection and cancer research on ways to improve recruitment and research strategies for cancer-related clinical trials. These measurements will help achieve how to be

clinical scientists for one-line doctor, make continuing medical education plan for the doctors just entering clinical work and build high effect and high quality clinical scientific research workstation. The article will also shape meaningful cancer research agendas to move the science forward from researchers, to doctors and cancer patients, and for future generations.

Methods

Clinical file management

Clinical files directly save one-hand data of patient and clinical assessment. Concretely, doctor will make primary clinical diagnosis for cancer patient from outpatient department through a series of laboratory and imaging examination.

Biospecimen collection

Patients with high-grade and -stage cancer were subjected to gene surveillances, which helped to find more potential therapeutic targets and treatment.

Ethics

The study was conducted according to the XXXX National Code for Health Research Ethics and the Declaration of Helsinki. Ethical approval to conduct this study was obtained from the ethics committee of the XXXX, after approval of the research protocol. Informed consent was obtained from all participants before enrollment in the study.

Educational Intervention

The educational intervention in accordance with framework of cancer was developed as previously described^{2,3}. The educational contents contain cancer warning signs and the role of healthy lifestyles on cancer prevention (Table 1)⁴. Professional researcher conducted the whole procedures.

Cancer Awareness: Warning Signs

We develop the Cancer Awareness Measure (CAM) with reference to prior studies on cancer². The CAM is planned to assess awareness of cancer in the manner of validated questionnaire.

Healthy Lifestyle

Healthy lifestyle were evaluated The following domains: smoking, high fat diet, physical activity (> 150 min/week), and fruits and vegetables intake^{5,6}.

Questionnaire Validity

QOL and satisfaction degree is based on assessment score from patients range from 1 to 10.

Statistical Analysis

All data are expressed as means $\pm$ standard error of the mean for each experimental group. Determination of statistical significance was performed by one-way analysis of variance followed by Tukey's multiple comparison for equal variances assumed, or by Kruskal–Wallis test followed by Dunn's Multiple Comparison for equal variances not assumed. Statistical analyses were performed based on Graph Pad Software. $P < 0.05$ was considered statistically significant.

Results

1. Clinical file management

Clinical files directly save one-hand data of patient and clinical assessment. Concretely, doctor will make primary clinical diagnosis for cancer patient from outpatient department through a series of laboratory and imaging examination. All patients are admitted to hospital to pursue needle biopsy. The tissues are cut into pieces to facilitate pathological diagnosis and make scoring (professional cancer grade system). These patients will be stratified into different treatment group based on treatment guidelines (NCCN) suggestions and self-choice from patient. Professional doctors will adjust these treatment recommendations according to patient assessments (Fig. 1).

2. Biospecimen collection

The samples were collected from blood and tissue and further subjected to ctDNA variation, CTC examinations and drug sensitive tests. Based on usual gene mutation of different urological tumors reported in literatures, we built a pool of gene examination. Patients with gene examination will get a report labeled in the form of the name and number of gene mutation and potential target drugs (Fig. 1).

3. Cancer research

The interplay between clinical and basic studies is the trend of current biomedicine development. In our urological unit, we implement the clinical trial based on patients combined with global clinical department and pharmaceutical companies, the basic researches based on animals and cells combined with local and global biomedical laboratories, and the translational studies based on the connection between clinical and basic science (Fig. 2). Our cancer research plan is based on patients and for them.

4. Sociodemographic characteristics of study participants

A total of patients participated in our database and received the whole content. The follow-up patients have increased year by year, from in 2005 to in 2020. These patients can be move to stratified analysis according to clinical stage, treatment choice and follow-up. See Fig. 3. Based on information from database, we have carried out bench-bed cross-study as above-mentioned for prostate cancer with gene mutation and special pathological type, including BRCA2 mutation and neuroendocrinal adenocarcinoma. Respective clinical data have been used for publication and III-phase clinical trials are going on.

5. Effects of the educational intervention for patient on awareness of warning signs for cancer

Baseline measurements revealed that patient has low awareness of the warning signs for cancer before educational intervention. Awareness of all warning signs for cancer showed significant increases across all measurements. See Table 2. Educational intervention for patient on awareness of warning signs for cancer is effective.

6. Effects of the educational intervention for patient on healthy lifestyles for cancer prevention

The educational intervention help patient decrease smoking and high-fat food consumption, and improve the practice of physical activity and the intake of vegetables and fruits. See Table 3. Educational intervention for patient on healthy lifestyles for cancer prevention is effective.

7. Questionnaire performance and reliability

We provided scores to assess the QOLS and satisfaction degree in the questionnaire, which suggested a strong level of internal consistency. Similarly, Pearson's correlation test showed strong the QOLS-SD reliability (over 0.72) for all items ($p < 0.05$). See Fig. 4. Through our systematic work in clinical files, the QOL of and communication with the patients is advanced, which is attributed to our suggestion on individual therapy.

8. Effects of the continuing medical education on study ability

The follow-up staff must hold basic clinical medical knowledge and carry out continuing medical training. In our unit, the recording time (RT) is increasingly shorter year by year, but more detailed than before in data collection (Fig. 5). These indicate that the ability of our follow-up staff is advanced through continuing medical education and study curves.

Discussion

Management on Clinical Sample

Some of patients are admitted to hospital for further operation treatment, radiotherapy or chemotherapy based on abovementioned assessment, of which the clinical information about basic characteristics and examination indexes are recorded in medical records^{7,8}. Some of patients are only follow-up in outpatient department and subjected to watchful waiting, active surveillance or drug therapy. Their files are recorded in outpatient records. Professional clinical researchers are recruited into our clinical work unit to specially take detailed notes and build information bank for the patients. Regular follow-up and data collection in outpatient view or telephone visit are administered by our clinical researchers. They will build files for

every patient and teach them to take changes in patient's condition. These data will be collected into our clinical information bank.

Achievement of Bed to Bench Translational Study

All the samples were categorized, endowed with labels and saved in biobank. Some professional researchers, educated in biomedical and archival science backgrounds, were employed to collect the samples, file the information and manage the banks. When needed to performed with biomedical studies, they will be used in DNA, RNA and protein assays in transcription and translation levels or made into RNA and tissue arrays to carry on biochemical and pathological experiments^{9,10}.

Analysis Based on Educational Intervention and Patient Feedback

Based on the feedback data of disease development and healthy style, we will reassess and provide better treatment or suggestion for patient. These data construct important parts prepared to publication after comparison analysis. Except these, reassessment on feedback data also help us conduct better medical training for our doctors and researchers^{8,11}.

Continuing Medical Education

Only be a doctor is not the destination for training undergraduates and interns. Future medical group need the clinical scientists, which hold medical and scientific background. They help providing professional and evidence-based medical consult for patient. For example, the results of genetic surveillance will screen targeting drug to combat cancer development¹². The data statistics based on patient and comparison with evidence-based publication will provide optimum treatment option for patients.

Conclusion

The standard administration of clinical sample and files provide us the achievement of bed to bench translational study. An educational intervention for educational communication in the framework of cancer control raised awareness for cancer prevention and improved healthy lifestyles. The data feedback, collection and analysis help give cancer survivors proper suggestion and improve our staff ability. These administration, analysis and suggestion on clinical files create the optimization for patient health achievement, medicine science study publication and individual career development. This also is future mode for clinical follow-up protocol (Fig. 6). Further randomized controlled studies are warranted.

Declarations

Authors' contributions

Not applicable.

Funding

This work was supported for Dali Tong Chongqing Science and Technology Commission (Basic and Frontier Research Project, Grant No: cstc2018jcyjA2133) and Chongqing Municipal Health Planning Commission (Science and Health Combined Medical Research Project, Grant No: 2018QNXM041).

Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Ethics approval and consent to participate

Not applicable.

Consent for publication

Not applicable.

Competing interests

Not applicable.

References

1. Haring RC, Henry WA, Hudson M, Rodriguez EM, Taulii M. Views on clinical trial recruitment, biospecimen collection, and cancer research: population science from landscapes of the Haudenosaunee (People of the Longhouse). *J Cancer Educ.* 2018;33(1):44-51.
2. Meneses-Echavez JF, Alba-Ramirez PA, Correa-Bautista JE. Raising Awareness for Lung Cancer Prevention and Healthy Lifestyles in Female Scholars from a Low-Income Area in Bogota, Colombia: Evaluation of a National Framework. *J Cancer Educ.* 2018;33(6):1294-1300.
3. Vanthomme K, Vandenheede H, Hagedoorn P, Gadeyne S. Evolution of educational inequalities in site-specific cancer mortality among Belgian men between the 1990s and 2000s using a "fundamental cause" perspective. *BMC Cancer.* 2017;17(1):470.
4. Meltzer LR, Meade CD, Diaz DB, et al. Development of a Targeted Smoking Relapse-Prevention Intervention for Cancer Patients. *J Cancer Educ.* 2018;33(2):440-447.
5. Maruthappu M, Watkins J, Noor AM, et al. Economic downturns, universal health coverage, and cancer mortality in high-income and middle-income countries, 1990-2010: a longitudinal analysis.

- Lancet*. 2016;388(10045):684-695.
6. Penson DF. Considering quantity and quality of life in metastatic castration-naive prostate cancer. *Lancet Oncol*. 2018;19(2):153-154.
 7. Jin J. Screening for Prostate Cancer. *JAMA*. 2018;319(18):1946.
 8. Riikonen JM, Guyatt GH, Kilpelainen TP, et al. Decision Aids for Prostate Cancer Screening Choice: A Systematic Review and Meta-analysis. *JAMA Intern Med*. 2019.
 9. Labrecque MP, Coleman IM, Brown LG, et al. Molecular profiling stratifies diverse phenotypes of treatment-refractory metastatic castration-resistant prostate cancer. *J Clin Invest*. 2019;130:4492-4505.
 10. Page EC, Bancroft EK, Brook MN, et al. Interim Results from the IMPACT Study: Evidence for Prostate-specific Antigen Screening in BRCA2 Mutation Carriers. *Eur Urol*. 2019.
 11. Fitzmaurice C, Abate D, Abbasi N, et al. Global, Regional, and National Cancer Incidence, Mortality, Years of Life Lost, Years Lived With Disability, and Disability-Adjusted Life-Years for 29 Cancer Groups, 1990 to 2017: A Systematic Analysis for the Global Burden of Disease Study. *JAMA Oncol*. 2019.
 12. Hwang LL. Educational Intervention on Undergraduate Cancer Awareness and Self-Directed Learning. *J Cancer Educ*. 2018;33(3):592-601.

Tables

Due to technical limitations, table 1, table 2 and table 3 are only available as a download in the Supplemental Files section.

Figures

Figure 1

Clinical and experimental workflow for cancer diagnosis, treatment and translational study;

Figure2

Figure 2

Bench-to-bedside workflow for cancer translational study

Figure3

Figure 3

Sum number of patients with cancer from 2005 to 2010

Figure4

Figure 4

Satisfaction score and QOLS assessment from 2005 to 2010

Figure5

Figure 5

Recording time of cancer from 2005 to 2010

Figure6

Figure 6

The coordination mode of doctor-patient-CRC triangle

Supplementary Files

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