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Analysis of Electrophoresis Detection of 47940 Cases in a Tertiary Academic China Hospital: A 6-year Retrospective Audit and Briefly Review

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Abstract **Background**: This audit provides baseline data on the prevalence, testing pattern and yield of electrophoresis tests performed over a 6-year period in a tertiary academic China hospital. To evaluate the adequacy of the electrophoresis test request. **Methods**: This was a retrospective audit of all SPE, UPE and IFE tests performed on new and follow-up adult patients (aged ≥18 years) from 2014 to 2019, using data from the Department of Laboratory Science of Jiangsu Province Hospital laboratory information system database. **Results**: A total of 47,940 cases of electrophoresis, there are 15,473 cases SPE tests (of which 25.6% were follow-up tests); have 12,531 cases UPE tests (10.2% of the tests were follow-up tests); have 19,327 cases SIFE tests (31.6% of which were follow-up tests). Hematology was the highest rate of submission and positive. SPE testing before IFE tests can effectively increase the positive rate of IFE. **Conclusion**: This audit provides baseline data on the prevalence of test requests, their source and the yield of electrophoresis testing in our laboratory. An increasing trend in SIFE and UIFE was evident.

Keywords: *electrophoresis, monoclonal gammopathies, accuracy, immunofixation*

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1. Introduction

Globally, healthcare systems are under pressure to reduce costs while continuing to provide quality services. Laboratory medicine has been targeted as a potential source of savings, with the implementation of principles of demand management and the efficient use of laboratory tests used as a means of cost reduction and viewed as a critical function of laboratory staffs [1].

Serum protein electrophoresis (SPE), urine protein electrophoresis (UPE), immunofixation electrophoresis (IFE) analysis are important tests used to diagnose and monitor monoclonal gammopathies (MGs) [2,3]. This audit provides baseline data on the prevalence, testing pattern and yield of electrophoresis tests performed over a 6-year period in a tertiary academic China hospital. To evaluate the adequacy of the electrophoresis test request.

2. Methods

2.1. Study Design

The study was a retrospective analysis. All the electrophoretic test data from the Department of Laboratory Science of Jiangsu Province Hospital (JSPH) from January 2014 to December 2019 were selected. Jiangsu Province Hospital is also named as The First Affiliated Hospital with Nanjing Medical University. It has a history of 80 years and is the former Clinic Affiliated with Jiangsu Medical College established in 1936.At present, the hospital is the best and biggest comprehensive hospital in Jiangsu, taking charge of four central roles for the whole province: medical treatment, medical teaching, scientific research, and hospital ethics activities. Till now there are 3,000 beds in the hospital, with more than 5,000 employees.

Inclusion criteria were all SPE, UPE and IFE tests conducted on new and follow-up adult patients (aged ≥18

years) presenting to JSPH. SPE, UPE and IFE tests conducted on patients aged <18 years were excluded.

2.2. Ethical Considerations

To ensure patient confidentiality, all personal identifying information on patients was removed, with only laboratory sample numbers used to label the data. Information pertaining to patient samples was restricted to members of the research team. The study was approved by the Health Research Ethics Committee of JSPH and was in accordance with the 2013 Declaration of Helsinki.

2.3. Laboratory Methods

The UPE tests were performed on the Sebia Hydrasys2 (Sebia, USA) semiautomated electrophoresis system using agarose. The SPE test was performed on the Sebia Hydrasys2 (Sebia, USA) semiautomated electrophoresis system using agarose before May 2019, and on V8 NEXUS - Automated Clinical Capillary Electrophoresis (Helena Laboratories, USA) after May 2019. The IFE tests were performed on the Sebia Hydrasys2 (Sebia, USA) semiautomated electrophoresis system using agarose before November 2018, and 9 people were tested per batch. Agarose gel electrophoresis using the SPIFE Touch semiautomatic system (Helena Laboratories, USA) after that, 15 parts for each test.

Our laboratory is accredited by CNAS ISO: 15189 certification system and subscribes to internal and externalproficiency testing schemes.

2.4. Data Analysis

Data were analysed using descriptive statistical techniques using Microsoft Excel version 14 (USA) and SPSS version 22 (USA) statistical software. Follow-up tests on the same patient were removed.

3. Results

3.1. Prevalence of Testing

A total of 15,473 SPE tests were performed on 11,513 individual patients (of which 25.6% were follow-up tests). A total of 12,531 UPE tests were performed on 11,258 individual patients (10.2% of the tests were follow-up tests). A total of 19,327 SIFE tests were performed on 13,211 individual patients (31.6% of which were follow-up tests). A total of 609 UIFE tests were performed on 392 individual patients over the three years from 2017 to 2019 (35.6% of the tests were follow-up tests). Of the 11,513 patients who underwent the SPE test, 5748 (49.9%) underwent the SIFE test. Of the 7,269 patients undergoing UPE testing in the three years from 2017 to 2019, 215 (2.9%) underwent UIFE testing (Table 1).

The number of various electrophoretic tests has increased year by year, with the highest growth rates of SIFE and SPE. The number of SIFE tests performed has steadily increased from 1,698 in 2014 to 5,713 in 2019, with an average annual growth rate of 39.4%. The number of SPE tests increased from 1,499 in 2014 to 6,414 in 2019, with an average annual growth rate of 54.7%, with the largest increase in 2019 compared to 2018, with an annual growth rate of 172.6% (Figure 1). After SIFE changed its testing equipment and increased the number of single batch inspections, the Turn-Around Time (TAT) dropped from 3.6 days to 2.2 days, and the monthly inspection quantity increased from 330 tests / month to 476 tests / month. After changing the detection method of SPE, the TAT decreased from 5.5 days to 1.3 days, and the number of monthly tests increased from 210 tests / month to 730 tests / month.

Table 1. Electrophoresis tests, 2014 - 2019

Test	Total tests, *N*	Tests excluding follow-up tests, *n*	Follow-up tests, %	Age	Gender ratio (male: female)
SPE	15473	11513	25.6	51.8±17.5	1.17
UPE	12531	11258	10.2	55.8±16.2	1.27
SIFE	19327	13211	31.6	51.4±18.1	1.28
UIFE*	609	392	35.6	61.4±10.6	1.06

* Since September 2017 period to carry out detection UIFE.

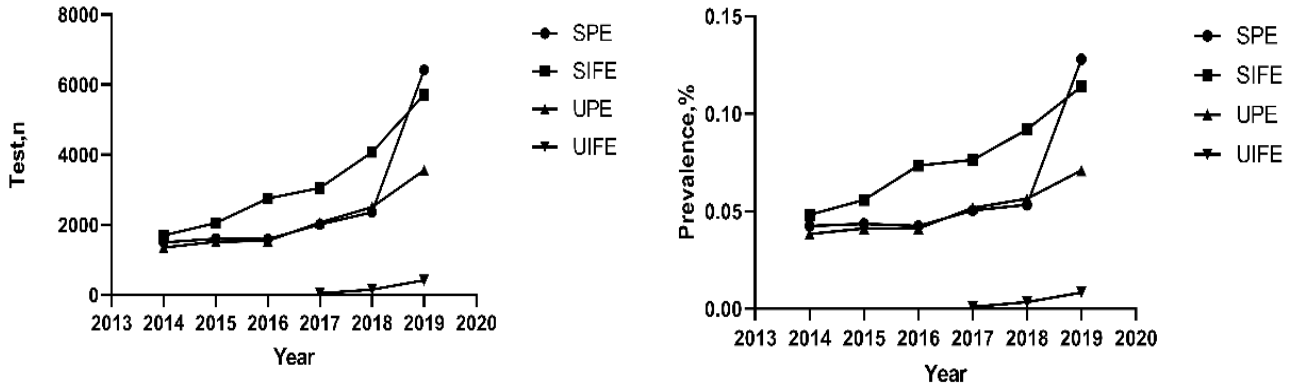

Figure 1. Numbers and Prevalence of SPE, UPE, SIFE and UIFE tests, 2014 - 2019

3.2. Sources of Test Requests and Test Yield

The overall positive rate of SIFE test was 27.47%, and the overall positive rate of UIFE test was 35.3%. The main sources of SIFE are hematology and nephrology patients. The number of outpatient and inpatient tests accounts for 92.26% of all SIFE tests. The main source of UIFE is hematology patients, accounting for 92.12% of all UIFE. The department with the highest positive SIFE test was the hematology department (39.7% of inpatients and 40.2% of outpatients). The departments with the highest UIFE test positive rate were also hematology (39.3% of inpatients and 27.2% of outpatients). (Table 2, Figure 2)

Among the 13211 patients who underwent the SIFE test, there were 5748 patients who underwent the previous SPE test, with a positive rate of 18.4%. No SPE test was performed, and there were 7,463 SIFE-only tests, with a positive rate of 10.7%, difference was statistically significant(P<0.001). Among them, the positive rate of SIFE for M protein positive was 86.7% (728/841). Of the 397 patients who underwent UIFE testing, 215 patients underwent UPE testing earlier, with a positive rate of 39.5%. No UPE test was performed, only 177 cases were detected for UIFE, the positive rate was 33.9%. (Figure 3)

Table 2. Yield for all SIFE and UIFE tests, 2014 - 2019

Test	Positive results, *n* (%)*	Negative results, *n* (%)**	Oligoclonal/polyclonal test results, *n* (%)	Total tests, *N*
SIFE	4519(23.4)	14018(72.5)	790(4.1)	19327
UIFE	215(35.3)	394(64.7)	0	609

*Positive results include the presence of an immunoglobulin monoclonal band with kappa or lambda light-chain restriction or the presence of free kappa and/or lambda light chains.
**Negative results include the absence of an immunoglobulin monoclonal band and absence of kappa or lambda light-chain restriction.

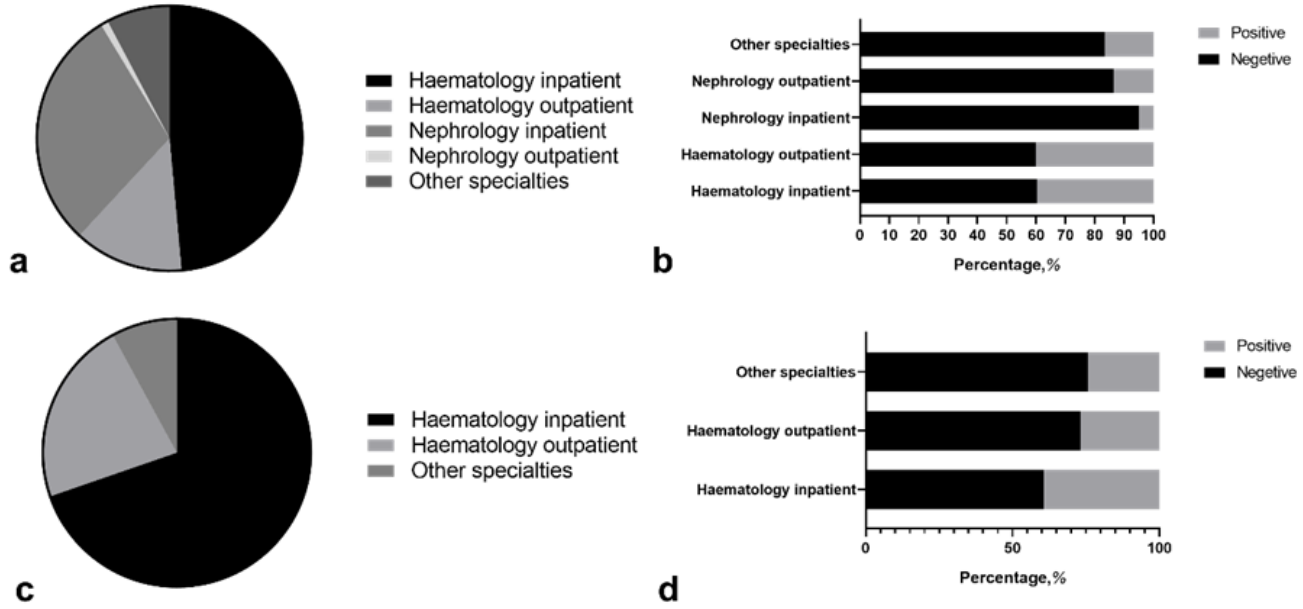

Figure 2. Positive yield for all SIFE by specialty, 2014 - 2019: a. The main sources of SIFE; b. Positive rate of SIFE main detection department; c. The main sources of UIFE; b. Positive rate of UIFE main detection department

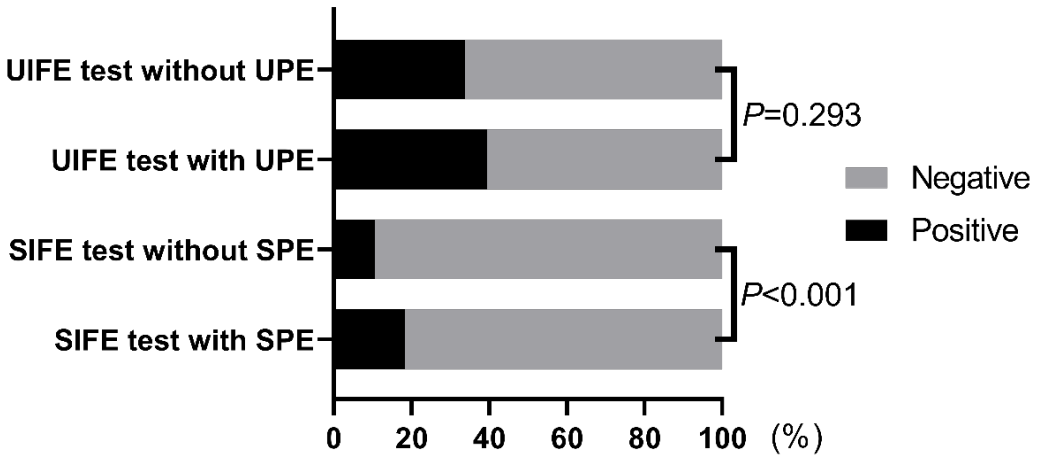

Figure 3. Comparison of SPE/UPE combined with IFE and IFE alone

4. Discussion

MGs are defined by the clonal expansion of plasma cells, resulting in the characteristic excretion of a monoclonal immunoglobulin (M-protein). MGs encompass a broad spectrum of clinical disorders ranging from asymptomatic, MG of undetermined significance (MGUS) to life-threatening diseases, such as multiple myeloma (MM) and amyloid light chain (AL) amyloidosis [4,5].

M-protein detection and quantification are integral parts of the diagnosis and monitoring of MG [6]. M-protein diagnostics is most commonly performed using serum electrophoretic methods, supplemented with additional assays for quantification and clonality testing. SPE, using either agarose gel (AGE) or capillary electrophoresis (CZE), is often the first test to screen for MG. SPE abnormalities are confirmed and isotyped using the more sensitive methods of immunofixation electrophoresis (IFE). A typical SPE tracing shows 6 protein fractions: albumin, α_1, α_2, β (which resolves into β_1 and β_2 peaks), and γ. The immunoglobulins IgG, IgA, IgM, IgD, and IgE are usually located in the γ region, although a paraprotein may migrate into the β even α_2 region on occasions, making diagnosis difficult.

An audit of SPE tests in a UK hospital servicing a population of 759 000 people found that 10 557 SPE tests were conducted in 2011, then 26% of requests for SPE tests were inappropriate. Most of the appropriate SPE test requests were from clinical haematology, renal medicine, rheumatology and geriatric clinical disciplines [7]. A study from Scotland shows that SPE has a role in differentiating between kidney-induced kidney injury and B-cell-induced kidney injury [8]. A recent retrospective audit revealing the need for IFE testing following identification of a suspicious SPE pattern [9].

This study evaluated the prevalence, test pattern, and yield of a 6-year electrophoresis test performed by a tertiary Class A hospital in Jiangsu Province, China. We found that from 2014 to 2019, the absolute number of electrophoretic tests and the percentage of visits to doctors showed an upward trend, which can be explained by doctors' higher awareness of electrophoretic tests. Compared with 2018, the growth rate of serum protein electrophoresis and serum immunofixation electrophoresis is very large in 2019, especially the serum protein electrophoresis increased from 2358 (2018) to 6414 (2019), an increase of 172.0%. This may be related to changes in detection methods and shortened TAT detection time. From November 2018, the number of detections in each batch of serum immunofixation electrophoresis was adjusted from 9 to 15. The average TAT time decreased from 3.6 days to 2.2 days. From May 2019, serum protein electrophoresis uses capillary electrophoresis. From the original 5.5 days to 1.3 days, it can be seen that the timely rate of inspection items can greatly affect the utilization rate of clinicians.

In terms of department distribution, 92.3% of the patients were detected in the two departments of nephrology and hematology (including outpatients and inpatients), but the positive rate was lower than that of other general hospitals shown in the literature. Especially the positive rate of nephrology patients was only 5.2%. This may be because the purpose of IFE testing in nephrology patients is to exclude renal damage caused by plasma cell diseases such as multiple myeloma, and the positive rate itself is not high. However, the positive rate of hematology patients is only 41.1%, which may be related to the detection method of the hospital. Because the TAT time of detecting SPE by agarose gel electrophoresis is longer (5.5 days), it is higher than the TAT time of IFE (3.6 days), Clinicians will use IFE instead of SPE for screening. On the other hand, as the largest general hospital in the province, the hospital receives many referral patients, and the positive rate may be lower than that of the first visit. Statistics show that among the 13211 SIFE patients tested, there were 5748 patients who had previously undergone SPE testing, with a positive rate of 18.4%. No SPE test was performed, and only 7463 cases were detected for SIFE, with a positive rate of 10.7%. The difference between the two was significant. Among them, there were 841 patients with SPE-positive M protein, and the SIFE-positive rate was 86.6%. We believe that the detection of SPE first, combined with clinical symptoms, can effectively exclude some patients with non-plasma cell disease, reduce unnecessary SIFE testing, reduce diagnosis and treatment costs, and improve detection efficiency. For nephrology patients, a quantitative assessment of serum / urine light chain can also be used to make a preliminary assessment of the source of renal injury.

5. Conclusion

This audit provides baseline data on the prevalence of electrophoresis testing, the source of test requests and test yield in our laboratory, providing useful data for future studies involving plasma cell disorders. Compared with hospitals of similar size in foreign countries, the coverage rate of our hospital's SPE test is relatively low, and the number of SIFE tests is more, which is related to the frequency of China's medical insurance policies and testing methods. Its lower yield is related to the nature of our hospital and the distribution of disease in the region. Against the background of increasing trends in IFE testing at our hospital, the proportion of negative IFE test results, particularly for UIFE, emphasises the value of clinical evaluation when interpreting electrophoresis results.

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Author Contributions

All the authors have accepted responsibility for the entire content of this submitted manuscript and approved submission.

Competing Interests

None of the authors have conflicts of interest to declare.

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