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BRIEF REPORT

Economic impact of a rapid, on-demand ADAMTS-13 activity assay for the diagnosis of thrombotic thrombocytopenic purpura

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Abstract

Background: Thrombotic thrombocytopenic purpura (TTP) is a rare, life-threatening thrombotic microangiopathy (TMA), characterized by ADAMTS-13 activity <10%. ADAMTS-13 activity assays are typically performed in reference laboratories with a turnaround time of several days. First-line treatment for TTP, therapeutic plasma exchange (TPE), typically starts while results are pending. The automated, on-demand HemosIL AcuStar ADAMTS-13 Activity assay provides results in under an hour, which could reduce unnecessary TPE use and associated costs.

Objectives: To estimate the hospital budget impact in the United States, United Kingdom, and France of using a rapid ADAMTS-13 activity assay.

Methods: We compared routine use of a rapid assay in adults with TMA with a scenario in which results take 3 days. Model structure and variables were based on published literature, plus survey and interviews of five clinicians from the three countries. Costs for the ADAMTS-13 activity assays and TPE were included.

Results: Model results suggest that if an on-demand, rapid ADAMTS-13 activity assay is used, US, UK, and French hospitals could save $18 million, £1.2 million, and €1.6 million annually, respectively. This equates to $10 788, £3497, and €4700 saved per patient with TMA in the United States, United Kingdom, and France. The model is most sensitive to the exact split of diagnoses of TMA cases, as savings accrue from non-TTP diagnoses.

Conclusions: In patients with TMA, use of a rapid, on-demand ADAMTS-13 activity assay such as the HemosIL AcuStar ADAMTS-13 Activity assay has the potential to be cost saving for hospitals.

KEYWORDS
ADAMTS-13 protein, cost savings, plasma exchange, thrombotic microangiopathies, thrombotic thrombocytopenic purpura

Essentials

- ADAMTS-13 assays are used in the differential diagnosis of thrombotic microangiopathy (TMA).
- Patients with TMA receive therapeutic plasma exchange (TPE) while they await assay results.
- We modeled the impact of a rapid assay that gives results within an hour rather than days.
- The assay could cut TPE use saving $18 million in the United States, £1.2 million in the United Kingdom, and €1.6 million in France annually.

1 | INTRODUCTION

Thrombotic thrombocytopenic purpura (TTP) is a rare thrombotic microangiopathy (TMA). Differential diagnosis includes atypical (complement-mediated) hemolytic uremic syndrome (aHUS), Shiga toxin–producing *Escherichia coli*–associated hemolytic uremic syndrome (STEC-HUS), or other TMAs caused by conditions such as malignancy or certain medications.

Diagnosis of TTP is time critical, as mortality is 90% without treatment.[1] Guidelines recommend initiating first-line treatment—therapeutic plasma exchange (TPE)—as soon as TTP is suspected, and ideally within 4 to 8 hours of the patient presenting.[1,2]

TTP is characterized by low activity levels (<10%) of a disintegrin and metalloproteinase with a thrombospondin type 1 motif member 13 (ADAMTS-13), the von Willebrand factor cleaving protease, in plasma. ADAMTS-13 activity assays to confirm TTP diagnosis are typically performed in specialized and reference laboratories, as most methods are complex and require specialist skills.[3-5] This can mean a turnaround time (TAT) of several days, due to time taken for sample transport as well as testing and reporting.[6,7] As a result, TPE is usually initiated empirically while results are pending.

HemosIL AcuStar ADAMTS-13 Activity (Instrumentation Laboratory, Bedford MA, USA) is an automated, on-demand assay with results available in under an hour. Use of this assay could allow more rapid diagnosis of TTP and reduce unnecessary TPE use in patients with other diagnoses, the need to transfer to more specialized hospitals,[8] and the risk of adverse events associated with TPE. Ruling out a TTP diagnosis more rapidly can also allow for earlier initiation of appropriate therapies, potentially improving patient outcomes. For example, earlier initiation of eculizumab in patients with aHUS is associated with a significantly reduced need for dialysis.[9]

We estimated the hospital budget impact of routine use of the HemosIL AcuStar ADAMTS-13 Activity assay on use of TPE in the United States, United Kingdom, and France.

2 | METHODS

We compared a rapid TAT scenario using an on-demand assay versus a standard TAT scenario in which it takes an average of 3 days to receive results. The treatment pathways and model variables were fixed values based on publications plus surveys and interviews with five clinicians from the three countries (see Tables 1 and 2 for details of model input parameters). The survey asked experts to validate assumptions about model parameters and the treatment pathway and suggest values for parameters such as the proportion of individuals with each diagnosis receiving TPE.

The model includes all adults hospitalized with TMA (due to TTP, aHUS, STEC-HUS, or other TMA diagnoses that would need differential diagnosis). The incidence of these conditions was assumed to be the same across all study countries. Population estimates used the most recent available data for each country. The proportion of patients with each diagnosis who received TPE and the duration for which this was received was based on expert responses to the survey. Costs to the hospital are for ADAMTS-13 activity assays and for any TPE received over 3 days. Cost estimates were obtained from the literature or national cost databases where available, with additional information obtained from expert personal communication and from the HemosIL AcuStar ADAMTS-13 Activity test manufacturer (Instrumentation Laboratory). Older cost estimates inflated to 2019 values using medical care inflation rates.

Based on guideline recommendations[1,10,11] and expert confirmation, we assumed that all patients with TMA would receive TPE until TTP was excluded based on the ADAMTS-13 assay result and clinical judgment. In the standard TAT scenario, it was assumed that most patients would receive TPE for 3 days, as used in previous modeling,[12] and consistent with expert responses in our survey. The US and UK experts indicated that tests to confirm STEC-HUS diagnosis would be expected back in 2 days, so for these countries it was assumed that TPE would be stopped after 2 days in patients with STEC-HUS.

In the rapid TAT scenario, it was assumed that once TTP was excluded, a decision on whether to initiate TPE would be based on clinical judgment. The rates of TPE use for each diagnosis were based on average expert estimations for each country. We conservatively assumed that patients with STEC-HUS would receive TPE at the same rates as those with aHUS until the results of the STEC-HUS test were received.

Modeling was carried out in Excel (Microsoft Corporation, Redmond, WA, USA). One-way sensitivity analyses were carried out for key variables where the literature or survey indicated uncertainty or variation in practice. A Consolidated Health Economic Evaluation Reporting Standards (CHEERS) checklist was completed for the study and is available from the corresponding author on request.

TABLE 1 Population and cost input parameters

Parameter	Value	Source	Notes
Adult population size (18+ y)	United States: 256 943 733 United Kingdom: 52 673 433 France: 52 641 954	US Census Bureau[18,19] UK Office for National Statistics[20,21] French National Institute of Statistics and Economic Studies[22]	Most recent available data were used: • United States: population estimates from December 9, 2020, age breakdown from July 1, 2019 • United Kingdom: mid-2019 • France: January 2020
Annual incidence of TMA	6.5 per million	Calculation based on Bendapudi et al,[23] Schönermarck et al,[24] Veyradier et al[13]	Same incidence used across study countries
Breakdown of individuals with TMA by diagnosis	23.0% TTP (1.5/m) 13.4% aHUS (0.9/m) 2.3% STEC-HUS (0.1/m) 61.4% Other (4/m)	Calculation based on Bendapudi et al[23] and Schönermarck et al[24]	Same breakdown of TMA used across study countries
Cost of one TPE treatment	United States: $5103.70 United Kingdom: £1822.50 France: €3032.05	United States: Average of figures from Goshua et al,[25] Connell et al[4] and Kim et al[3] United Kingdom: NHS reference costs 2019 (average of costs for the procedure performed as nonelective short and elective or long stays)[26] plus cost for Octaplas[27](14 units estimated[7]) France: Public hospital tariff for plasma exchange from ATIH (tariff for GHS9615 GHM28Z16Z)[28] plus costs for fresh frozen plasma (F. Provôt, personal communication)	Older cost estimates inflated to 2019 values using medical care inflation rates
Cost per HemosIL AcuStar ADAMTS-13 Activity test	United States: $500 United Kingdom: £365.69 France: €412.98	Instrumentation Laboratory, personal communication	Average cost provided in $ and converted to £ and € using xe.com
Cost per standard ADAMTS-13 activity test	United States: $312.62 United Kingdom: £100 France: €89	United States: Average of figures from Connell et al,[4] Kim et al,[12] Kim et al[3] United Kingdom: University College London Hospitals (Health Services Laboratories)[29] France: Eurofins Biomnis[30]	Older cost estimates inflated to 2019 values using medical care inflation rates

Abbreviations: aHUS, atypical (complement-mediated) hemolytic uremic syndrome; ATIH, Agence Technique de l'Information sur l'Hospitalisation; NHS, National Health Service; STEC-HUS, Shiga toxin–producing Escherichia coli–associated hemolytic uremic syndrome; TMA, thrombotic microangiopathy; TPE, therapeutic plasma exchange; TTP, thrombotic thrombocytopenic purpura.

TABLE 2 Percentage of patients with each diagnosis receiving TPE and duration of TPE in standard and rapid turnaround time (TAT) scenarios for each country*

	US		UK		France	
Diagnoses	Standard TAT scenario	Rapid TAT scenario	Standard TAT scenario	Rapid TAT scenario	Standard TAT scenario	Rapid TAT scenario
TTP	100%, 3 days	100%, 3 days	100%, 3 days	100%, 3 days	100%, 3 days	100%, 3 days
aHUS	100%, 3 days	10.3%, 3 days	100%, 3 days	50%, 3 days	100%, 3 days	100%, 3 days
STEC-HUS	100%, 2 days	10.3%, 2 days	100%, 2 days	50%, 2 days	100%, 3 days	100%, 3 days
Other diagnoses	100%, 3 days	5%, 3 days	100%, 3 days	0%, 0 days	100%, 3 days	10%, 3 days

Abbreviations: aHUS, atypical (complement-mediated) hemolytic uremic syndrome; STEC-HUS, Shiga toxin–producing *Escherichia coli*–associated hemolytic uremic syndrome; TAT, turnaround time; TPE, therapeutic plasma exchange; TTP, thrombotic thrombocytopenic purpura.

*Assumptions based on guidelines[1,10,11] and expert opinion.

3 | RESULTS AND DISCUSSION

3.1 | Base case results

Model results are summarized in Table 3. The rapid TAT scenario prevents 1215 people from having unnecessary TPE in the United States (3611 treatments), 238 people (711 treatments) in the United Kingdom, and 190 people (570 treatments) in France. This results in total savings nationally for US, UK, and French hospitals of $18 million, £1.2 million, and €1.6 million annually, respectively.

3.2 | Results of sensitivity analyses

One-way sensitivity analyses were conducted evaluating the impact of:

1. TPE not being performed for any patients with non-TTP diagnoses after TTP is excluded in the rapid scenario.
2. TTP being more common and "other" diagnoses less common.
3. Reducing the proportion of patients with "other" diagnoses who have ADAMTS-13 activity testing.
4. Varying the percentage of patients with HUS who receive TPE after TTP is excluded.

Table 4 summarizes the results of these sensitivity analyses.

If TPE is not initiated for any patient in whom TTP is excluded after ADAMTS-13 activity testing, this increases savings to $19.3 million in the United States, £1.3 million in the United Kingdom, and €2.3 million in France. This represents the maximum savings possible in the model (if all other parameters remain constant).

We selected an incidence of 1.5 per million for TTP in our base case, as reported by the French National Reference Center for Thrombotic Microangiopathies, which collects data on all TTP cases nationally.[13] This is a relatively low incidence for TTP, with estimates of up to 3.5 per million in the United States[14] and 6 per million in the United Kingdom.[15] Solely increasing the incidence of TTP in the model would not have a large impact as TPE use for these patients does not differ between the two scenarios.

Therefore, we looked at the impact of keeping the overall incidence of TMA the same, but increasing the proportion of TMA cases that were TTP (from 23% to 50%, ie, to about 3.3 per million) and reducing the proportion of "other" diagnoses (from 61% to 34%, ie, to about 2.2 per million). This reduced savings by between 36% and 47% across the countries.

Experienced clinicians may be able to exclude TTP for some patients based on clinical judgment, without the need for ADAMTS-13 activity testing. This may particularly be the case for those with "other" TMA diagnoses that are, for example, secondary to malignancy or use of certain medications. If only 50% of those with "other" diagnoses require ADAMTS-13 activity testing, this reduces savings by 41% to 51%. (Reducing the incidence of "other" diagnoses by 50% would have the same effect.)

Finally, less use of TPE in the aHUS group led to reduced savings, and more use of TPE led to increased savings, but differences were not substantial.

TABLE 3 Summary of results of the model base case

	US	UK	France
Total cases of TMA	1678	344	344
TTP cases	385	79	79
aHUS cases	225	46	46
STEC-HUS cases	38	8	8
Other TMA diagnoses	1030	211	211
Number of patients avoiding unnecessary TPE	1215	238	190
Number of TPE treatments prevented	3611	711	570
Savings per patient with TMA	$10,788	£3479	€4700
Savings for a hospital serving a catchment area with 1m adults	$70,496	£22,854	€30,710
Total annual savings nationally	$18m	£1.2m	€1.6m

Abbreviations: aHUS, atypical (complement-mediated) hemolytic uremic syndrome; STEC-HUS, Shiga toxin–producing *Escherichia coli*–associated hemolytic uremic syndrome; TMA, thrombotic microangiopathy; TPE, therapeutic plasma exchange; TTP, thrombotic thrombocytopenic purpura.

TABLE 4 Results of sensitivity analyses (annual national savings)

Scenario	United States	United Kingdom	France
(1) No TPE initiated after TTP excluded	$19.3 million	£1.3 million	€2.3 million
(2) TTP accounts for 50% TMAs, and "other" 34%	$11.5 million	£0.7 million	€0.9 million
(3) Only 50% of "other" diagnoses get ADAMTS-13 activity test	$10.7 million	$0.7 million	€0.8 million
(4) % with aHUS who get TPE after TTP ruled out (ranges from country experts except for France)	High estimate (31%): $17.3 million Low estimate (0%): $18.5 million	High estimate (100%): £1.1 million Low estimate (0%): £1.3 million	High estimate not applicable (100% used in base case) Low estimate (0%): €2.1 million

Abbreviations: aHUS, atypical (complement-mediated) hemolytic uremic syndrome; TMA, thrombotic microangiopathy; TPE, therapeutic plasma exchange; TTP, thrombotic thrombocytopenic purpura.

3.3 | Limitations and considerations

In some more specialized hospitals, rapid tests are already in use, so some of the estimated savings will already have been recognized. Hospitals that do not currently have the instrumentation to perform rapid tests would have an initial capital investment for the equipment. This was not included in the model for several reasons. National figures on what proportion of hospitals already have the Hemosil AcuStar are not available. Also, the instrumentation can perform multiple different tests and not solely the ADAMTS-13 assay; therefore, costs would need to be considered across the range of tests for which it is used and for the life span of the equipment, rather than solely for the ADAMTS-13 assay within the single year covered by our model.

Our base case assumption of an average 3-day turnaround for standard testing has been used in other analyses[12] and was validated in our expert survey. Turnaround times of up to a week or longer for reference laboratory testing have been reported in some literature.[4,9,11] Longer turnaround times for standard testing would mean greater potential savings with rapid testing.

There is uncertainty in several of the variables used in the model. TTP is rare, and there are limited national-level data on its incidence. There are also very limited published estimates of the breakdown of TMAs by diagnosis. In addition, practice is likely to vary between different hospitals nationally and internationally (as indicated in our expert survey). We also surveyed only a small sample of clinicians.

The final diagnosis of TTP is clinical, and the model assumes that clinical diagnosis is accurate regardless of the assay used, as it will be based on overall clinical picture and not solely assay results. A high level of agreement has been reported between the Hemosil AcuStar ADAMTS13 Activity and other ADAMTS13 activity assays, with sensitivity ranging from 90.1% to 100%, and specificity from 94.6% to 100%.[5,16,17] If in some cases clinical picture is not consistent with rapid assay results, additional ADAMTS-13 activity testing through reference laboratories may be needed.[16]

4 | CONCLUSION

In patients with TMA, use of a rapid, on-demand ADAMTS-13 activity assay such as the HemosIL AcuStar ADAMTS-13 Activity assay has the potential to be cost saving for hospitals.

The findings of our model are consistent with other studies that have also suggested that rapid turnaround ADAMTS-13 activity assays can produce cost savings through reducing TPE use.[3,7,12]

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RELATIONSHIP DISCLOSURE

The research was funded by Instrumentation Laboratory, but the Economist Intelligence Unit (EIU) maintained editorial independence throughout. All authors are (or were at the time of the research) employed by the EIU, who receive funding for projects from commercial companies such as Instrumentation Laboratory.

AUTHOR CONTRIBUTIONS

RC conceptualized and supervised the study. AW developed and ran the model. RM provided clinical input on the patient pathway to inform model structure, identified data points, and performed model checking. KS assisted in identification of experts and data points. AS managed the study and provided feedback on the model. All authors assisted in development of the expert survey and contributed to the final manuscript.

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