UNITED STATES DISTRICT COURT
DISTRICT OF MAINE

ANTON K. SAMAAN,	)	
	)	
Plaintiff,	)	
	)	
v.	)	CV-09-656-B-W
	)	
ST. JOSEPH HOSPITAL, et al.,	)	
	)	
	)	
Defendants.	)	

ORDER ON MOTION *IN LIMINE*

Based on a relatively scant record, the Court denies Dr. David Kaplan's motion to exclude the expert testimony of Dr. Ravi Tikoo concerning the likely consequences of the failure to administer tissue plasminogen activator (t-PA) to the Plaintiff within three hours of the onset of his stroke symptoms.

I. STATEMENT OF FACTS

A. Mr. Samaan's Stroke and Treatment at St. Joseph

On January 14, 2006, Anton K. Samaan boarded a flight in Milan, Italy to return to New York, New York, after visiting his family in Egypt for the holidays. During the flight, Mr. Samaan got up from his seat and headed toward the plane's galley for a cup of tea. When Mr. Samaan reached the galley, "he was confronted by a flight attendant who told him that he appeared sick." *Compl.* ¶ 9 Attach 2 (Docket #1). The flight attendant called for doctors on the plane, and at approximately 11:30 am, a doctor diagnosed him with "a likely stroke in progress."

Id. at ¶ 10. In accordance with the doctor's instructions, the pilot diverted the plane to the nearest airport. *Id.*

The plane landed in Bangor, Maine and Mr. Samaan reached the emergency department at St. Joseph not later than 12:40 p.m., where he was treated by emergency room physician David Kaplan, M.D. *Id.* ¶ 11, 15. Dr. Kaplan did not administer t-PA. *Id.* ¶ 11. Mr. Samaan has suffered "severe deficits as a result of the ischemic stroke he suffered on 01/14/06." *Id.* ¶ 13. He has filed this suit against St. Joseph and Dr. Kaplan, alleging that Dr. Kaplan's failure to administer t-PA violated the standard of medical care and caused him severe damages. *Id.* ¶ 22.

B. Ravi Tikoo, M.D.

1. The Defendant's Characterization of Dr. Tikoo's Opinion

Mr. Samaan designated Dr. Ravi Tikoo, a neurologist, to testify as an expert on his behalf.[1] Dr. Tikoo will opine that "Dr. Kaplan's decision not to administer t-PA proximately caused [Mr. Samaan's] alleged injuries." *Def. David Kaplan's Mot.* in Limine *To Exclude Test. of Ravi Tikoo, M.D.* at 2 (Docket # 26) (*Def.'s Mot.*). At his deposition, Dr. Tikoo "testified that the authoritative and definitive study, on the efficacy of t-PA to achieve better outcomes for ischemic stroke patients is the 1995 study titled 'Tissue Plasminogen Activator for Acute Ischemic Stroke,' by the National Institute of Neurological Disorders and Stroke (NINDS) t-PA Stroke Study Group." *Id.*; *See* Attach. 1 (Docket # 26) (NINDS Study). Dr. Tikoo "confirmed not only that the NINDS study is the 'generally accepted article' in this area, but also

[1] Strangely, neither Dr. Kaplan nor Mr. Samaan attached the Plaintiff's expert designation. Instead, they have referred to snippets of Dr. Tikoo's deposition testimony. It would have been helpful if the parties had provided a broader context.

that it is the basis for his conclusions in this case, and that there was nothing independent of the NINDS study that caused Dr. Tikoo to form the opinions that he did." *Def.'s Mot.* at 2.

Dr. Tikoo confirmed that the NINDS Study "was a randomized, double blind, placebo-controlled study wherein a group of subjects was administered t-PA, and a separate control group was not given t-PA despite the fact that its constituents fell within the standard three-hour window for the administration of t-PA following the onset of ischemic stroke symptoms." *Id.* He agreed that the NINDS Study "showed that when the results for the placebo group are compared to the results of the t-PA group, the percentage of 'favorable outcomes' increased by 12 percent for the t-PA patients, indicating a 12 percent absolute increase in the number of patients that ended up with minimal or no disability from stroke as a result of receiving t-PA." *Id.* at 2-3. Despite statistics to the contrary, Dr. Kaplan says that Dr. Tikoo's methodology was flawed for arriving at his opinion that "a patient would have a 51 percent or better chance of improvement if he was given t-PA as opposed to being given none." *Id.* at 3.

2. The Plaintiff's Characterization of Dr. Tikoo's Opinion

Although Mr. Samaan agrees that Dr. Tikoo relied on the NINDS Study, he presents a different view of Dr. Tikoo's opinion testimony. Dr. Tikoo notes that the conclusion of the NINDS Study was:

> Despite an increased incidence of symptomatic intracerebral hemorrhage, treatment with intravenous t-PA within three hours of the onset of ischemic stroke improved clinical outcome at three months.

Pl.'s Mem. in Opp'n to Def. Kaplan's Mot. in Limine *to Exclude Test. from Ravi Tikoo, M.D.* at 5 (Docket # 30) (*Pl.'s Mem.*). Dr. Tikoo explained that "the 1995 NINDS Study could not be considered an 'absolute' indicator, because the definitions employed to denote 'improvement' were very limited, and did not encompass all of the patients who may have experienced a benefit from t-PA." *Id.* In Dr. Tikoo's view, "it is undeniable that there was a greater than fifty percent (50%) improvement in the patients who met the study's requirements for 'improvement' in clinical outcome after receiving t-PA, compared to those who did not." *Id.* To buttress his opinion, Dr. Tikoo pointed out that the NINDS Study itself referred to a variety of measurements, including the Barthel Index and the Odds Ratio, and under both of these measurement standards, the extent of improvement exceeded fifty percent. *Id.* at 5-6. Finally, Dr. Tikoo pointed to a later double-blind, placebo controlled, randomized study – ECASS-III - that was published in 2008 in the New England Journal of Medicine that encompassed 110 European hospitals in 15 countries, involved 821 patients and "demonstrated that fifty-two percent (52%) of patients receiving t-PA reached a clinically favorable outcome." *Id.* at 6-7.

3. Dr. Kaplan's Reply

In his Reply, Dr. Kaplan says that Dr. Tikoo's methodology is "patently flawed, unreliable, and outside the bounds of Federal Rule of Evidence 702" and must be excluded. *Def. David Kaplan, M.D.'s Reply in Support of Defs.' Mot.* in Limine *To Exclude Test. of Ravi Tikoo, M.D.* at 1 (Docket # 42) (*Def.'s Reply*). First, he says that since Dr. Tikoo acknowledged that the NINDS Study is the "gold

standard," "his attempt at reliance on more recent studies would be inapposite anyway." *Id.* at 3. Dr. Kaplan asserts that the NINDS data "are crystal clear: 34% of patients have a favorable outcome from t-PA, when measured by National Institutes of Health Stroke Scale." *Id.* "If a patient has a 34% chance of favorable outcome if given t-PA, it cannot be said that he *more likely than not* will have a favorable outcome if given t-PA." *Id.* (emphasis in original).

Dr. Kaplan disparages Dr. Tikoo's "clums[y] attempts to distort" the NINDS Study. *Id.* Dr. Tikoo had noted that the increase from 21% (the percentage who recovered without t-PA) to 34% (the percentage who recovered with t-PA) is 13% and 13% is more than half of 21%. *Id.* Describing the calculation as "inapt," Dr. Kaplan says it "does not even approach the legally required showing that *the plaintiff himself* had a greater than 50% chance of improved outcome had he been given t-PA." *Id.* at 3-4 (emphasis in original). He goes on to say that even if the Odds Ratio is used, the "law does not require a showing that a t-PA patient is *more likely than a placebo patient* to avoid injury, the law requires that a t-PA patient is *more likely than not* to avoid injury." *Id.* at 4 (emphasis in original). Similarly, Dr. Kaplan attacks Mr. Samaan's reference to ECASS-III as containing a recurring error of methodology, namely in asserting that its 52.4% figure is appropriate because it must be compared with 45.2% of the placebo group, who had a favorable outcome, an absolute increase of only 7.2%. *Id.* at 5.

II. DISCUSSION

A. The Maine Standard

In *Phillips v. Eastern Maine Med. Center*, 565 A.2d 306 (Me. 1989), the Maine Supreme Judicial Court wrote that "to establish liability in a medical malpractice case, the plaintiff must show that the defendant's departure from a recognized standard of care was the proximate cause of the injury." *Id.* at 307. Under Maine law, a person alleging harm from professional negligence has the burden to prove that it is more likely than not that the professional's negligence caused harm. *Merriam v. Wanger*, 2000 ME 159 ¶ 17, 757 A.2d 778, 782; *Wetmore v. MacDonald, Page Schatz, Fletcher & Co., LLC*, 476 F.3d 1, 4 (1st Cir. 2007) (stating that "[i]n order for the negligent act to constitute proximate cause, the act or omission must be a substantial factor in bringing about the harm and the injury incurred must have been a reasonably foreseeable consequence") (citation omitted).

B. Different Efficacy Based on Different Studies and Outcome Measures

Dr. Tikoo observes that the percentages Dr. Kaplan relies on from the NINDS Study reflect only one measure of potential favorable responses to t-PA treatment. The authors of the NINDS Study concluded that:

> As compared with patients given placebo, patients treated with t-PA were at least 30 percent more likely to have minimal or no disability at three months, as measured by the outcome scales (absolute increase in favorable outcome, 11 to 13 percent).

NINDS Study at 6. Despite this 30% figure, Dr. Tikoo maintained that for Mr. Samaan, his chances for improvement with t-PA would have been more than 50%. First, Dr. Tikoo emphasized that the three month figures from the NINDS Study addressed the percentage of stroke victims who have "minimal or no disability" after

three months. He characterized the NINDS Study as failing to address those individuals who obtain "a middle score or having some disability that's above baseline." *Dep. of Ravi Tikoo* 24:15-19. In other words that 30% figure does not include patients who may have benefitted from t-PA but did not recover to the level of "minimal or no disability."

Second, Dr. Tikoo pointed out the 2008 ECASS-III Study, which reported that among those patients who received t-PA between 3 and 4.5 hours after the onset of an ischemic stroke, 52% reached a clinically favorable outcome according to outcome measures that may have differed from the "minimal or no disability" standard in the NINDS Study. Finally, Mr. Samaan attached to his Response a 2003 article from the American Stroke Association entitled "Impact of Establishing a Primary Stroke Center at a Community Hospital on the Use of Thrombolytic Therapy: The NINDS Suburban Hospital Stroke Center Experience", which was authored in part by Paul Nyquist, another of the Plaintiff's experts. *Additional Attchs. Filed in Resp. to Def's Mot.* Attach. 4 (Docket #35) (*Nyquist Article*).. This article, which addressed the impact of timely t-PA therapy on stroke victims, stated:

> Sixteen patients (36%; 95% CI, 24 to 51) had a very favorable recovery (mRS≤1), and 20 (45%; 95% CI, 31 to 61) recovered functional independence (mRS≤2).

Nyquist Article at 3. Mr. Samaan argues that the Nyquist article confirms that "there is significant statistical and clinical support for Dr. Tikoo's expressed opinions and conclusions." *Pl.'s Mem.* at 9.

C. A Synthesis

Putting all of this together, solely for purposes of this motion, the Court assumes that the standard of care for treatment of ischemic stroke patients includes the administration of t-PA barring specific contraindications for patients who present for treatment within three (3) hours of the onset of symptoms. *Pl.'s Mem.* at 2. It also assumes that Mr. Samaan fit within the category of patients who would have been suitable for t-PA. The question then is whether the failure to administer t-PA more likely than not caused harm.

There is a nationally recognized study from 1995, which concludes that the percent of patients who receive timely t-PA within 3 hours of the onset of ischemic stroke symptoms and who within three months recover to the point of having minimal or no disability is 34%, a percentage that falls below the Maine more probable than not standard for causation in professional negligence claims. Dr. Tikoo contends that this figure fails to account for the prospect of varying degrees of partial recovery and he has expressed the opinion that it is more likely than not that Mr. Samaan suffered some harm from Dr. Kaplan's failure to administer t-PA. He relies on a study that addresses a 52% clinically favorable outcome percentage for patients who receive t-PA beyond the three hour window. Mr. Samaan supports Dr. Tikoo's opinion with a 2003 study that suggests that the percentage of patients who benefitted from timely t-PA is as high as 81%. *See Nyquist Article* at 3. These studies all conclude that t-PA is effective in treating ischemic stroke, but their discrepancies leave t-PA's efficacy imprecise.

Based on the record before it, Dr. Kaplan has not convinced the Court that Dr. Tikoo's opinion testimony should be summarily excluded. The Court is cognizant that it is generally up to a fact-finder to weigh the experts' presentation of the relevant data and determine whether the evidence establishes that Mr. Samaan was more likely than not to have benefited from t-PA. *See Merriam*, 2000 ME 159 ¶ 17, 757 A.2d 778, 782. In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), the United States Supreme Court wrote that "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." *Id.* at 596. Where the parties' experts disagree about the weight and applicability of various studies and permissible conclusions, the Court will not exclude Dr. Tikoo's testimony at least on this record.

D. Other Authority

Lastly, Dr. Kaplan points to two federal court decisions in which similar expert testimony on the efficacy of t-PA has been excluded. *See Def.'s Mot* at 9-10 (citing *Smith v. Bubak*, No. CIV 08-44023, 2010 WL 605269 (D.S.D. Feb. 18, 2010) *and Young,* 2006 WL 1984613. The evidentiary bases in both *Young* and *Smith*, particularly *Smith*, were much more extensive than what has been presented here. If the evidentiary record were more fully developed, the Court might arrive at the same result as in *Smith* and *Young*; however, the Court concludes that it would benefit from a greater understanding of the foundation for the experts' opinions and from more illuminating and less adjectival advocacy.

III. CONCLUSION

The Court DENIES David Kaplan, M.D.'s Motion *in Limine* (Docket # 26).

SO ORDERED

/s/ John A. Woodcock, Jr.
JOHN A. WOODCOCK, JR.
CHIEF UNITED STATES DISTRICT JUDGE

Dated this 14th day of October, 2010