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Original Article / Özgün Makale

Variations in international normalized ratio applications among Turkish cardiovascular surgeons: Daily practice versus Guidelines

Türk kalp damar cerrahları arasında uluslararası normalleştirilmiş oran uygulamalarındaki farklılıklar: Günlük uygulamaya kıyasla kılavuzlar

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ABSTRACT

Background: In this study, we aimed to investigate the degree of guideline compliance for warfarin use among the Turkish cardiovascular surgeons in daily practice.

Methods: Between May 2016 and June 2016, a total of 314 cardiovascular surgeons were included in this study. The participants were administered an 18 item-questionnaire for warfarin use, which was approved by the Executive Board of the Turkish Society of Cardiovascular Surgery for the issues related with warfarin use. The questionnaire was sent via electronic mail to the members of the society twice and data were collected.

Results: Based on the collected data, a report was prepared by the Working Group for Cardiovascular Basic Sciences of the Turkish Society of Cardiovascular Surgery. It was found that the Turkish cardiovascular surgeons followed lower international normalized ratio targets for mitral valve repair and bioprosthetic valves at any position. For mechanical valve prostheses and atrial fibrillation, they mostly applied targets defined in the guidelines.

Conclusion: Brief courses or acknowledgements should be planned by our society to disseminate this critical guideline information. This would increase awareness and increase guideline-based practice which is evidence-based and universally accepted. Translations of guidelines may be also shared on the website of the society, if copyright issues are settled. For the international normalized ratio monitorization, the use of point-of-care testing, a simple and quick test, should be encouraged.

Keywords: Guideline; heart valve prosthesis; international normalized ratio; Warfarin.

ÖZ

Amaç: Bu çalışmada, Türk kalp damar cerrahlarının günlük uygulamada kılavuzlara uyumluluk derecesi araştırıldı.

Çalışma planı: Bu çalışmaya Mayıs 2016 - Haziran 2016 tarihleri arasında toplam 314 kalp damar cerrahı dahil edildi. Katılımcılara Türk Kalp Damar Cerrahisi Derneği Yönetim Kurulu tarafından onaylanmış varfarin kullanımına ilişkin 18 maddelik bir anket uygulandı. Anket, dernek üyelerine elektronik posta yoluyla iki kere gönderildi ve veriler toplandı.

Bulgular: Toplanan verilere göre, Türk Kalp Damar Cerrahisi Derneği Kalp Damar Cerrahisi Temel Bilimler Çalışma Grubu tarafından bir rapor hazırlandı. Türk kalp damar cerrahlarının mitral kapak tamiri ve biyoprotez kapak replasmanında daha düşük uluslararası normalleştirilmiş oran hedeflerini takip ettiği tespit edildi. Mekanik kapak protezlerinde ve atriyal fibrilasyonda, çoğunlukla kılavuzda tanımlanmış hedefleri uyguluyorlardı.

Sonuç: Önemli kılavuz bilgilerini yaygınlaştırmak için derneğimiz tarafından kısa kurslar veya bilgilendirmeler planlanmalıdır. Bu, duyarlılığı ve kanıta dayalı ve evrensel olarak kabul edilen kılavuza dayalı uygulamayı da artıracaktır. Telif hakkı sorunlarının çözüme kavuşturulması durumunda, derneğin web sitesinde kılavuzların çevirileri yayımlanabilir. Uluslararası normalleştirilmiş oranların takibi için, basit ve hızlı bir test olan hasta başı test kullanımı özendirilmelidir.

Anahtar sözcükler: Kılavuz; kalp kapak protezi; uluslararası normalleştirilmiş oran; Varfarin.

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"*The can of un-coagulated blood lying on the floor of Link's laboratory was to change the course of history and little did Link know what the implications would be*".[1] Karl Paul Link, the Wisconsin Alumni Research Fund Scientist (WARF), and his senior student Wilhelm Schoeffel had invented warfarin in 1941, which both gave and took many lives.[1] The drug has celebrated its 75th birthday this year. It was used as a rodenticide which soon became one of the most prescribed drugs over time.[1] It was used for patients with heart failure and stroke in 1950s, soon employed for various cardiovascular pathologies and cardiovascular prostheses.[1] Warfarin has been a great friend and foe of cardiovascular surgeons, since its advent.

However, the requirement for blood monitorization has limited its efficacy and applicability. The international normalized ratio (INR) testing has become the standard parameter and currently it can be performed either as laboratory measurement or point-of-care (POC) testing. In the cardiovascular field, different target INRs are recommended for different pathologies by guidelines.[2]

In this study, we aimed to document the variability in the INR testing and therapeutic goals in different cardiac pathologies and cardiac prostheses among the Turkish cardiovascular surgeons in daily practice. We also aimed to document the difference between real-world practice and guideline recommendations and to create awareness on appropriate use of warfarin.

MATERIALS AND METHODS

Between May 2016 and June 2016, all participant cardiovascular surgeons were administered an 18 item-questionnaire for warfarin use, which was developed by the author Durukan, Ahmet Baris on behalf of the Working Group for Cardiovascular Basic Sciences of the Turkish Society of Cardiovascular Surgery and was approved by the Executive Board of the Turkish Society of Cardiovascular Surgery for the issues related with warfarin use (Figure 1). As the number of cardiovascular surgeons registered in the Turkish Society of Cardiovascular Surgery is 1,194, the questionnaire was sent via electronic mail to the members of the society twice (4th and 27th May, 2016). Repetitive attendance was prevented by means of the software program provided by the electronic mail corporation (Pleksus Bilişim Teknolojileri AŞ, Ankara, Turkey). The system was closed on 21st June, 2016.

Statistical analysis

No statistical analysis was need for this study. Data were expressed in percentage.

RESULTS

Of 1,194 cardiovascular surgeons, 314 (26.3%) who filled out the questionnaire were included in the study.

Based on the collected data, it was found that the Turkish cardiovascular surgeons followed lower INR targets for mitral valve repair (MVr) and bioprosthetic valves at any position. For mechanical valve prostheses and atrial fibrillation (AF), they mostly applied targets defined in the guidelines. The results of the questionnaire are depicted in Table 1.

DISCUSSION

In the present study, we investigated the degree of guideline compliance for warfarin use among the Turkish cardiovascular surgeons in daily practice.

In a previous study, a questionnaire was administered by the CTSNet on the nomenclature used for aortic root components in 2011.[3] In the aforementioned study, the sample size was 534 among over 10,000 CTSNet members. Therefore, the percentage of the participants in our study can be regarded as quite high, compared to the aforementioned study designed by the very superior society. However, this participation rate is relatively low to make a direct assumption on the behaviors of the Turkish cardiovascular surgeons. Nonetheless, we believe that this was a pilot study to shed light on this subject.

Warfarin-derived anticoagulation effect is by means of inhibition of vitamin K epoxide reductase which decreases the amount of vitamin K necessary for the production of intrinsic coagulation factors.[4] However, the further mechanisms for coagulation and anticoagulation are beyond the scope of this study. Warfarin can be defined as a two-sided blade, since the low INR levels achieved may cause thrombosis, whereas high levels may cause life-threatening hemorrhage.[4] Therefore, therapeutic algorithms were defined and pharmacogenetic data for the patient management is currently available online (www.warfarindosing.org) and also as smartphone applications (i.e., iWarfarin). Along with that, 63.7% of participants do not rely on the safety of warfarin. To the best of our knowledge, this is the first study to ask cardiovascular surgeons whether they trust the safety of warfarin.

As very well-known, warfarin increases the thrombotic tendency in the first few days, until the therapeutic INR level is reached.[4] Among the Turkish cardiovascular surgeons, 83.4% used low-molecular-weight heparin (LMWH) during this period, while 1.9% used conventional heparin, 13.7% used both, and

1. In any patient using warfarin for any indication, do you think warfarin is safe despite its effectiveness?
   a) Yes
   b) No
2. Which anticoagulation regimen do you prefer while therapeutic international normalized ratio level is reached in a patient using warfarin?
   a) Low molecular weight heparin
   b) Conventional heparin
   c) Either
   d) None
3. Which of the below do you prefer for international normalized ratio monitorization?
   a) Hospital laboratory
   b) Ambulatory international normalized ratio monitorization
   c) Either
4. Do you think ambulatory international normalized ratio monitorization is safe?
   a) Yes
   b) No
   c) Not sure
5. Which anticoagulation regimen do you employ in a patient with isolated permanent atrial fibrillation?
   a) New oral anticoagulants
   b) Warfarin
   c) Either
6. Which of the below is therapeutic international normalized ratio range in a patient with isolated permanent atrial fibrillation?
   a) 1.5-2.0
   b) 2.0-2.5
   c) 2.0-3.0
   d) 2.5-3.5
   e) >3.5
7. In a patient with mitral valve repair including ring insertion, without atrial fibrillation, do you use warfarin, if yes, for how long?
   a) No
   b) Yes; 1 month
   c) Yes; 3 months
   d) Yes; lifelong
8. If you use warfarin for the above patient, which of the below is therapeutic international normalized ratio range?
   a) 1.5-2.0
   b) 2.0-2.5
   c) 2.0-3.0
   d) 2.5-3.5
   e) >3.5
9. In a patient with bioprosthetic valve replacement in any position, without atrial fibrillation, do you use warfarin, if yes, for how long?
   a) No
   b) Yes; 1 month
   c) Yes; 3 months
   d) Yes; lifelong
10. If you use warfarin in a patient with bioprosthetic mitral valve replacement without atrial fibrillation, which of the below is therapeutic international normalized ratio range?
    a) 1.5-2.0
    b) 2.0-2.5
    c) 2.0-3.0
    d) 2.5-3.5
    e) >3.5
11. Which of the below is therapeutic international normalized ratio range in a patient with mechanical mitral valve replacement?
    a) 1.5-2.0
    b) 2.0-2.5
    c) 2.0-3.0
    d) 2.5-3.5
    e) >3.5
12. In a patient with bioprosthetic aortic valve replacement without atrial fibrillation if you use warfarin, which of the below is therapeutic international normalized ratio range?
    a) 1.5-2.0
    b) 2.0-2.5
    c) 2.0-3.0
    d) 2.5-3.5
    e) >3.5
13. Which of the below is therapeutic international normalized ratio range in a patient with mechanical aortic valve replacement?
    a) 1.5-2.0
    b) 2.0-2.5
    c) 2.0-3.0
    d) 2.5-3.5
    e) >3.5
14. Which of the below is therapeutic international normalized ratio range in a patient with mechanical aortic and mechanical mitral valve replacement?
    a) 1.5-2.0
    b) 2.0-2.5
    c) 2.0-3.0
    d) 2.5-3.5
    e) >3.5
15. In a patient with aortic valve replacement and/or mitral valve repair/replacement, if tricuspid valve repair or bioprosthetic valve replacement is performed concomitantly, do you intend to change therapeutic international normalized ratio range?
    a) Yes, increase
    b) Yes, decrease
    c) No
16. In a patient with aortic valve replacement and/or mitral valve repair/replacement, if mechanical tricuspid valve replacement is performed concomitantly, do you intend to change therapeutic international normalized ratio range?
    a) Yes, increase
    b) Yes, decrease
    c) No
17. Which of the below is therapeutic international normalized ratio range in a patient with tricuspid valve replacement without atrial fibrillation?
    a) 1.5-2.0
    b) 2.0-2.5
    c) 2.0-3.0
    d) 2.5-3.5
    e) >3.5
18. In which of the below cases do you add acetyl salicylic acid for treatment?
    a) Mitral valve repair
    b) Bioprosthetic valve replacement
    c) Mechanical valve replacement
    d) Atrial fibrillation

Figure 1. Variations in international normalized ratio applications among Turkish cardiovascular surgeons: Daily practice versus Guidelines.

1.0% used none of them. The 2014 American Heart Association and the American College of Cardiology (AHA/ACC) Guidelines for the Management of Patients with Valvular Heart Disease is incapable of making a discrimination between the use of either LMWH or fractional heparin, until the INR target is achieved,

Table 1. The questionnaire and results

	n	%
1. Is warfarin safe despite its effectiveness?		
Yes	114	36.3
No	200	63.7
2. Preferred AC regime until desired INR is achieved		
LMWH	262	83.4
Conventional heparin	6	1.9
Either	43	13.7
None	3	1.0
3. INR monitorization method		
Laboratory testing	277	88.2
POC testing	2	0.6
Either	35	11.1
4. Is POC testing safe?		
Yes	80	25.5
No	44	14
Not sure	190	60.5
5. Preferred AC regime in AF		
NOAC	108	34.4
Warfarin	112	35.7
Either	94	29.9
6. Target INR in AF		
1.5-2.0	25	8.0
2.0-2.5	154	49.0
2.0-3.0	117	37.3
2.5-3.5	18	5.7
>3.5	-	-
7. MVr, AF-, t Warfarin		
0	45	14.3
1 month	17	5.4
3 months	239	76.1
Life-long	13	4.1
8. MVr, AF-, Target INR		
1.5-2.0	54	17.2
2.0-2.5	138	43.9
2.0-3.0	90	28.7
2.5-3.5	31	9.9
>3.5	1	0.3
9. Any BP, AF-, t Warfarin		
0	37	11.8
1 month	14	4.5
3 months	254	80.9
Life-long	9	2.9
10. BP, MVR, AF-, Target INR		
1.5-2.0	33	10.5
2.0-2.5	133	42.4
2.0-3.0	111	35.4
2.5-3.5	37	11.8
>3.5	-	-
11. mMVR, Target INR		
1.5-2.0	1	0.3
2.0-2.5	26	8.3
2.0-3.0	100	31.8
2.5-3.5	185	58.9
>3.5	2	0.6
12. BP AVR, AF-, Target INR		
1.5-2.0	81	25.8
2.0-2.5	153	48.7
2.0-3.0	61	19.4
2.5-3.5	17	5.4
>3.5	2	0.6
13. mAVR, AF-, Target INR		
1.5-2.0	9	2.9
2.0-2.5	140	44.6
2.0-3.0	129	41.1
2.5-3.5	36	11.5
>3.5	-	-
14. mAVR+mMVR, Target INR		
1.5-2.0	-	-
2.0-2.5	16	5.1
2.0-3.0	58	18.5
2.5-3.5	232	73.9
>3.5	8	2.5
15. AVR ± m/BP MVR/MVr+ BP TVR/TVr, ↑INR?		
↑	74	23.6
↓	1	0.3
-	239	76.1
16. AVR ± m/BP MVR/MVr+ mTVR, ↑INR?		
↑	182	58
↓	1	0.3
-	102	32.5
>3.5	29	9.2
17. mTVR, AF-, Target INR		
1.5-2.0	4	1.3
2.0-2.5	28	8.9
2.0-3.0	68	21.7
2.5-3.5	167	53.2
>3.5	47	15.0
18. AC regime + ASA		
MVr	121	24.3
BP R	150	31.1
m R	109	21.9
AF	118	23.7

AC: Anticoagulation; INR: International normalized ratio; LMWH: Low-molecular-weight heparin; POC: Point-of-Care; AF: Atrial fibrillation; NOAC: Novel oral anticoagulant; MVr: Mitral valve repair; t: Time; BP: Bioprosthesis; mAVR: Mechanical aortic valve replacement; BPTVR: Bioprosthetic tricuspid valve replacement; TVr: Tricuspid valve repair; ASA: Acetylsalicylic acid; R: Replacement.

although it recommends the mandatory use of either one.[2] Regarding the INR monitorization, the guidelines recommend a program for the patient education and periodic surveillance for the INR monitorization. Hospital-based anticoagulation monitoring is also considered more effective in terms of lower complication and lower hemorrhagic complication rates.[2] However, self-monitoring with home-based INR measurement devices are recommended for more educated and motivated patients.[2] According to our meticulous review of the studies including home-based measurement devices, contradictory results are

available. Home-based devices were reported to be reliable, since the proportion of time spent with the INR target range (TTR: time to therapeutic range) was higher with these devices, whereas deviation from the target was higher in laboratory testing.[5] However, during a follow-up period of 4.2 years, only 13.5% of the patients continued to use home-based devices due to high costs, although all reported that these devices increased their quality of life.[6] According to the guidance on the Use of Point-of-Care Testing of International Normalized Ratio for Patients on Oral Anticoagulant Therapy, the POC testing represent an accurate alternative to laboratory testing.[7] In addition, in a systematic review and cost-efficacy analysis including 47 studies, it was concluded that the INR results achieved with POC testing were comparable with standard laboratory devices with more rapid accurate results.[8] In our study, 88.2% of the participants used the laboratory testing as the sole method. Only 25.5% of the participants defined POC testing as safe, while 60.5% was unsure. This can be attributed to the fact that the reimbursement does not cover POC testing in Turkey. However, particularly for educated patients, the use of POC testing may be recommended to increase the quality of life. Furthermore, additional acknowledgements should be given to physicians on the safety and efficacy of POC testing.

On the other hand, the target INR levels vary depending on the existing pathology. In case of AF, if anticoagulation is indicated, an INR range between 2.0 and 3.0 is targeted.[9] The precise target was given by 37.3% of the participants; however, a target range of 2.0 to 2.5 was given by 49.0%. Overall, the results are consistent with the guideline recommendations. The same guideline recommends either warfarin or novel oral anticoagulant (NOAC), if anticoagulation is recommended.[9] One-third of the participants preferred using warfarin, one-third using NOACs, and one-third using either. This represents the wide use of NOACs among the Turkish cardiovascular surgeons. It is quite satisfactory, as they offer advantages over warfarin, most strikingly the lack of need for monitorization, lower hemorrhagic complications, and higher efficacy to prevent thromboembolic complications of AF. However, the use of NOACs in patients with prosthetic heart valves is contraindicated.[9]

Currently, there are two available guidelines on valvular heart disease which include the recommendations on the use of warfarin and the target of INR for prosthetic cardiac valves. The American guidelines are more recent (2014) and define precise target INR levels based on the type and position of the prosthetic valves,[2] while the European guidelines do not define similar targets, but recommend for valve thrombogenicity and patient risk factors[10] (Table 2). In principle, in the American guidelines, it is recommended to specify an INR target recognizing 0.5 INR units on each side to avoid values consistently near the upper or lower edge of the range.[2] In both, for mechanical valves, lifelong therapy is indicated.[2,10]

Table 2. Target international normalized ratio levels based on the European Society of Cardiology/ European Association for Cardio-Thoracic Surgery Guidelines on valvular heart disease[10]

	Patient-related factors*	
Prosthesis thrombogenicity†	-	+
Low	2.5	3.0
Medium	3.0	3.5
High	3.5	4.0

* MVR/TVR: Prior thromboembolism; AF: Any degree of mitral stenosis; Left ventricular EF <%35; † Low: Carbomedics, Medtronic Hall, St. Jude Medical, ON-X; Medium: other bileaflet valves; High: Lillehei-Kaster, Omniscience, Starr-Edwards, Bjork-Shiley and other tilting disc valves.

In patients with bioprosthetic mitral valve replacement or MVr, anticoagulation for three months is recommended to achieve an INR of 2.5 (Class IIa).[2] The European guidelines also recommend three-month anticoagulation therapy as Class IIa indication in mitral or tricuspid bioprostheses and MVr.[10] Among our study population, 76.1% and 80.9% preferred using anticoagulation for three months in MVr and mitral bioprostheses, respectively. However, considering the target INR, in MVr, 28.7% participants followed an INR target of 2.0 to 3.0, which is acceptable, while 43.9% followed an INR target of 2.0 to 2.5, which may be considered as a low target range. In bioprosthetic mitral valve replacement, 35.4% used an INR target of 2.0 to 3.0, which is acceptable, while 42.4% used an INR target of 2.0 to 2.5, which may be again defined as a low target range. Based on these findings, we can conclude that the Turkish cardiovascular surgeons tend to practice with lower range targets due to the concerns about hemorrhagic complications, which may not be safe, but still questionable.

In addition, in mitral valve replacement patients with a mechanical prosthesis, an INR target of 3.0 is recommended (Class I).[2] A total of 58.9% of the participants defined the therapeutic INR target as 2.5 to 3.5, which is consistent with the current guidelines, and 31.8% as 2.0 to 3.0, which is lower than the predefined targets.

Anticoagulation to achieve an INR of 2.5 is recommended for patients with aortic bioprosthetic valves for three months (Class IIa).[2] The European guidelines recommend three-month anticoagulation therapy as Class IIa indication in aortic bioprosthesis.[10] In this study, 80.9% of the participants used warfarin for three months. Considering the target INR, 19.4% followed an INR target of 2.0 to 3.0, which is acceptable, while 48.7% followed an INR target of 2.0 to 2.5, which is low than the predefined targets, in patients with an aortic bioprosthesis. we believe may be increased as outlined above for MVr and mitral bioprosthesis.

In addition, in aortic valve replacement patients with a mechanical prosthesis, an INR level of 2.5 is recommended (Class I).[2] If an additional thrombotic risk factor, such as AF, is present, a target INR of 3.0 is recommended (Class I).[2] In our study, 41.1% of the participants followed an INR target of 2.0 to 3.0, which is consistent with the guidelines, while 11.5% followed an INR target of 2.5 to 3.5, which is acceptable, but slightly higher than the predefined targets. In the present study, we did not include patients with an additional thrombotic risk factor, which yielded variable results. It is, however, noteworthy that 44.5% of the participants, that is almost half, defined their target range as 2.0 to 2.5, which is low and probably may not be safe for mechanical aortic prosthesis.

On the other hand, the European guidelines do not define a target INR range for aortic + mitral mechanical valve prosthesis. However, since a target INR of 3.0 for mechanical mitral valve replacement is recommended,[2] this can be used as the target for aortic + mitral mechanical valve prosthesis, as it also covers the recommended 2.5 target for aortic valve replacement. In our study, 73.9% of the participants followed an INR target of 2.5 to 3.5, which is consistent with the guidelines.

In both guidelines, it is not defined to make a change in the target INR, when a valve repair or bioprosthetic replacement in tricuspid position is made in addition to aortic and mitral valve replacement,[2,10] which is also the answer for 76.1% of our participants. For mechanical tricuspid valve replacement in addition to aortic and mitral valve replacement, the same is relevant; however, 58.0% of our participants tended to increase their defined target INRs. In the European guidelines, therapeutic range for mechanical tricuspid valve replacement is not specified.[2] Hence, we can assume that the same target for mitral valve replacement (3.0) is also valid for tricuspid valve replacement. Similarly, in our study, 53.2% of the participants defined their range as 2.5 to 3.5, which is acceptable.

In patients with mechanical valve prosthesis, additional antiplatelet therapy with 75 to 100 mg acetylsalicylic acid (ASA) is recommended as Class I indication in the American Guidelines[2] and as Class IIa indication in the European guidelines.[10] In patients with bioprosthetic aortic or mitral valves, the same regimen is recommended as a Class IIa indication in the American Guidelines.[2] European Guidelines recommend ASA for three months in aortic bioprosthesis.[10] However, in the AF guidelines, an additional advantage of warfarin+ASA over warfarin alone has not been reported.[9] In our study, 24.3% prescribed ASA following MVr, 30.1% following bioprosthesis implantation, 21.9% following mechanical valve implantation, and 23.7% for patients with AF. In our questionnaire, the first 17 questions had only one answer, while the last question had more than one possible answers.

Of note, it should be kept in mind that the guidelines always assist clinicians in medical decision-making process, as they summarize widely acceptable approaches based on available scientific data. They define practices which cover the majority of patients, although ultimate judgment should be always made by the clinician herself/himself, as s/he is the only one examining that particular patient. Some patients require deviations which are absolutely appropriate and necessary. On the other hand, the results of this study show that the guideline recommendations are not practiced, as much as it should be.

In conclusion, according to the results of this study, it is obvious that there are differences between the guideline recommendations and the practice of the Turkish cardiovascular surgeons. However, the results can be also defined as subjective, since the answers given in the questionnaire can be different than the surgeon's practice. In addition, for mitral valve repair and bioprosthetic valves at any position, the Turkish cardiovascular surgeons follow lower target international normalized ratio ranges which may be increased for the patient safety, although this issue is questionable, since the main goals of individual practice are defined by the guidelines and personal and/or institutional experience. For mechanical prosthesis and atrial fibrillation, the majority of surgeons follow more precise ranges. Based on our study results, we recommend brief courses or acknowledgements planned by our society to disseminate guideline information. This would increase awareness and increase guideline-based practice which is evidence-based and universally

accepted. Translations of guidelines may be also shared on the website of society, if copyright issues are settled. For the international normalized ratio monitorization, the use of point-of-care testing, a simple and quick test, should be encouraged.

Declaration of conflicting interests

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