Traditional Tibetan medicine in China: A systematic overview of randomized clinical trials

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Abstract

Background: Traditional Tibetan medicine (TTM) plays an important role in the health care system of China. Little is known about the current evidence of TTM’s clinical research in China.

Methods: Randomized controlled trials (RCTs) of TTM therapies conducted in China were searched in PubMed, Cochrane Library, two major Chinese electronic databases, and two Tibetan medical journals from their inception to June 2014. Qualitative analysis and reporting quality assessment were performed. The protocol was registered in PROSPERO (No: CRD42013006881).

Results: A total of 227 RCTs involving 29,179 participants were included. They were heterogeneous in terms of study size, sites, treated conditions, interventions, measured outcomes, and quality. 103 diseases or symptoms were reported in the included trials. TTM interventions used in the RCTs consisted of drug treatments and non-drug treatments including bloodletting and moxibustion, in which Tibetan patent medications for oral use were tested in 175 studies and for external use in 47 studies. 93.8% (213/227) of the trials reported superior effect of TTM over control interventions. Only 7.9% (18/227) of the trials described details of random sequence generation, 3.5% (8/227) described details of blind.

Conclusions: Clinical research in TTM in China covers whole medical systems. Data from RCTs showed that TTM might have potential benefit for the management of many diseases. Studies on definitive health outcomes could be systematically reviewed in order to provide more information on TTM’s efficacy. More efforts should be made to improve the quality of RCTs in China and support TTM’s further clinical applications.

Keywords: Tibetan traditional medicine; Randomized controlled trial; Review; China

Introduction

Traditional Tibetan medicine (TTM), also called “Ggso ba rig pa” in Tibetan, is a centuries-old traditional medical system based on the beliefs and practices of Tibetan culture. Originated from 2300 years ago, TTM absorbed plenty of medical theories and clinical techniques from early traditional Indian, Chinese, and Greco-Arab medicine in the 8th century, and has developed into a unique and mainstream medical system in Tibet since then [1,2]. Currently, TTM still plays an important role in health care system of China, especially in Tibetan regions. In Tibet Autonomous Region (TAR) and other provinces of Tibetan regions, the number of physicians practicing TTM was over 1200 in 1993 [3], and rose to at least 5000 in 2010 according to official statistics [4,5]. Additionally, many conventional western medicine physicians in Tibetan regions often incorporate TTM diagnostic and treatment into their clinical practices. In interior China, a majority of Tibetan patent medications are available in pharmacies and hospitals.

In TTM, the fundamental theory is “three elements” theory, consisting of “rLung”, “mKhris-pa”, and “Badkan”. Among the three elements, rLung represents wind or air, governing the respiratory system, blood circulation, sensory organs, and movement; mKhris-pa represents fire, helping digestion,
accelerating the decomposition of waste, absorbing heat energy from food, and producing heat energy. Badkan represents water and earth, providing nutrition for the body to maintain moisture, and is responsible for digestive and metabolic systems [6]. It is necessary to maintain the balance of three elements so as to keep normal functions of human body. A complex approach such as pulse analysis, urinalysis, palpation, and inquiry is employed for diagnosing illnesses. Treatments for restoring and maintaining balance between these elements mainly include dietary and behavior modification, medicines composed of natural materials and external therapy (e.g. medicated baths, acupuncture, moxibustion, yoga, etc.). Based on the general principle of holism and individualized treatment, TTM is believed to have potential benefits for the management of many diseases, like circulatory and psychosomatic disorders [7–9].

In recent decades, evidence-based medicine (EBM) has become increasingly important for traditional medicine resulting in clinical studies being conducted not only in China but in western countries, aiming to evaluate TTM’s effectiveness and safety. In 2013, a systematic review including 40 TTM clinical studies available in western countries was published [9], providing readers with meaningful data on status of TTM’s clinical research in the west. However, no Chinese or Tibetan publications were included in that review. In China, though TTM has been used as an important complementary treatment for a long time, there has been no systematic summary of clinical research on TTM. Therefore, this study systematically searched and reviewed the TTM randomized clinical trials (RCTs) conducted in China, in order to summarize the situation and identify common trends in this field.

Methods

Protocol and registrations

The protocol of this systematic overview was registered in PROSPERO funded by the UK National Institute for Health Research (CRD42013006881 Available from http://www.crd.york.ac.uk/PROSPERO/display_record.asp?ID=CRD42013006881). The protocol was presented in Supporting Information Captions 1 (S1).

Eligibility criteria

All randomized clinical trials investigating the use of TTM in treating diseases and being conducted in China were eligible for inclusion. No restriction on language and publication type was applied. Trials were excluded if any of the following are identified: (1) treatment group used some other medical treatments integrated with TTM interventions (for example, a western medicine drug plus a Tibetan patent medicine), and control group only used the same TTM interventions with treatment group. (2) Any duplicate publications identified were removed and only assessed once.

Search strategy

Electronic literature searches were carried out in PubMed, Cochrane Library (Issue 6, 2014), China National Knowledge Infrastructure (CNKI) and Wanfang Database. The details of search strategy were as follows:

1. “Medicine, Tibetan Traditional” [Mesh] AND (random [All Fields] was conducted in searching PubMed).
2. “Tibetan medicine” [Title, Abstract, Keywords] and “random*” [Search All Text] were conducted in searching “Trials” database of Cochrane Library.
3. (“zangyi” OR “zangyao” OR “zangxiyi jiehe”) [Theme] and “suiji” [All Text] were applied in searching CNKI.
4. (“zangyi” OR “zangyao” OR “zangxiyi jiehe”) [Title, Keywords] and “suiji” [All Text] were applied in searching Wanfang Database.

(Note: “zangyi” means TTM; “zangyao” means traditional Tibetan pharmacy; “zangxiyi jiehe” means integration of TTM and western medicine; “suiji” means random*. All of them are pinyin of Chinese character.)

Tibetan literature was hand-searched in two Tibetan medical journals (in Tibetan language): China’s Tibetan Medicine and Traditional Tibetan Medical Education and Research, for any Tibetan literature that had not yet been included in electronic databases yet. Databases were searched from their inception up until June 2014.

Study selection

Three researchers independently identified and checked each study against the inclusion criteria. H.L. and Q.W. selected studies from electronic databases. H.L. and Z.X.L.B. selected studies from two Tibetan medical journals (2007–2014). Firstly, the titles and abstracts of the search results were screened, and then full papers for all possibly relevant trials were obtained. Secondly, irrelevant and duplicated papers were excluded. Lastly, the remaining papers were re-checked by all researchers together, and then the final studies were included for the review.

Data extraction

A structured data extraction form was designed (H.L. and G.J.Z.). Three authors (H.L., Q.W., and Z.X.L.B.) used the form to extract the data independently. Any disagreements among the authors were discussed for consensus. The data extraction form involved study information as followed: (1) citation; (2) study design: study sites, participants, interventions in treatment and control groups, course of treatment, outcomes; (3) study methodology elements: randomization method, allocation concealment, blinding, and outcome measures and summary of results.

Quality assessment

Methodological quality of included studies was evaluated using criteria from the Cochrane Handbook for Systematic
**Abbreviations:** PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses; CNKI: China National Knowledge Infrastructure;

Fig. 1. PRISMA Flow chart: literature searching and study selection.

Reviews of Interventions [10]. Studies were appraised according to the risk of bias for each item, including completeness of reporting on generation of random allocation sequence, allocation concealment, blinding, and outcome. The quality of all included studies was categorized as low/unclear/high risk of bias. Trials that met all the criteria were categorized as low risk of bias, those that met none of the criteria were categorized as high risk of bias, and the rest were categorized as unclear risk of bias if insufficient information was available to make a judgment.

**Data analysis**

Data analysis was presented by counts, percentage and frequency. Microsoft Excel (version 2010) was applied for data extraction and analysis. RevMan software 5.2 was to be applied to conduct meta-analysis if the trials had a good homogeneity of study design, participants, interventions, control, and outcome measures.

**Results**

**Study selection**

Searches of the four databases and two journals identified 1005 papers. The majority were ineligible on reading the titles and abstracts. After duplicates among databases and irrelevant articles were removed, the remaining 266 papers were identified for full text review. Finally, 227 studies were included (Fig. 1).

The references were presented in Supporting Information Captions 2 (S2).

Publication year of included studies ranged from 1989 to 2014. The quantity of publications increased especially after 2009. There were a larger number of studies in the past four years (between 2011 and 2014) compared with other years (n = 101 studies, 44.5%) (Fig. 2). Of these included studies, one was published in English [11], and the remaining 226 were in Chinese. None were in the Tibetan language. All studies were conducted in China.

Fig. 2. Publication number of randomized clinical trials of traditional Tibetan medicine conducted in China.
Among the 227 studies, a majority of 213 (93.8%) reported trials with 2 arms, and 14 reported 3 or more arms in one study. The duration of the studies ranged widely from several days to 10 months. 22 studies did not report this item.

Interventions in the treatment group involved TTM interventions alone (149 studies), TTM combined with TCM treatments (42 studies), and TTM combined with conventional western medicine treatments (36 studies).

TTM interventions could be divided into two categories: drug treatments for oral or external use (including Tibetan patent medications, decoctions, medicated bath, retention enema, etc.) and non-drug treatments (including bloodletting and moxibustion). The majority of studies used oral Tibetan patent medications, accounting for 77.1% (175/227) of the studies. The second most frequently used treatments were Tibetan patent medications for external use, accounting for 20.7% (47/227). The five most common treatments investigated in the included trials were Xiaotong paste (22 studies), Qingpeng ointment (20 studies), Nengxiao 6 capsule (14 studies), Duyiwei capsule (12 studies), and Guijin 25 pill (8 studies). Xiaotong paste and Qingpeng ointment were produced by Tibet Cheezheng Tibetan Medicine Co., Ltd. Nengxiao 6 capsule (also called zhiyue drugpa in Tibetan) was produced by Tibet Tibetan Medicine Group Co., Ltd. Duyiwei capsule was produced by Gansu Duyiwei Biological Pharmaceutical Co., Ltd. Guijin 25 pill (also called aolse nyer Lang in Tibetan) was produced by several pharmaceutical companies including Cheezheng Tibetan Medicine and Crystal Beads Tibetan Medicine Group.

A whole medical system approach with complex TTM interventions was used in 19 studies, in which patients in TTM groups were given different Tibetan patent medicines or adjusted Tibetan patent medicines at different times within one day, and adjusted Tibetan patent medicines were performed by adding relevant Tibetan medicinal powders to patent medicines according to the patient’s TTM syndrome on an individual basis.

In control group, the interventions could be divided into four categories: TCM treatments (23.3%, 53 studies), conventional western medicine treatments (69.2%, 157 studies), placebo or blank (The term ‘blank’ in this context means that none of interventions is used for participant) control (2.6%, 6 studies), and other TTM treatments (10.1%, 23 studies). The combination of interventions from two categories was used in 4 studies’ control groups. A majority (93.4%, 71/76) of TCM and TTM treatments were patent medicines approved by China’s Food and Drug Administration, 5.3% (4/76) were decoctions, and 1.3% (1/76) was acupuncture. In placebo or blank control category, 4 studies used capsule placebo [13–16], 1 used ointment base for placebo comparing with ointment [17]; 1 used blank control
Effects and safety of TTM interventions

Outcome measures

Assessed outcomes included effective rate, clinical symptoms (such as symptom score, or symptom relieving time), laboratory tests, clinical tests (such as blood pressure, muscular tension, or function score), final outcome indexes (such as mortality rate, recurrence rate, or events rate), and others, such as quality of life, microbiology, histology, and iconography. The most frequently reported outcome index was ‘effective rate’. This was a composite index involving the improvement of symptoms, signs, laboratory tests, and others together, and usually the effectiveness of intervention was classified into three or four grades: cured, (marked effective), effective, ineffective. This outcome measurement has been widely used in TTM and TCM clinical research in China for decades mainly due to the guidelines for clinical research on Chinese new herbal medicines [19]. Among the included 227 studies, 187 (82.4%) used for effectiveness assessment; however, the majority did not report adequate information for each outcome, and great inconsistency was found on the methods for grading effective rate among these studies (Table 2).

Effects

Some diseases were researched in several trials. For example, chronic hepatitis B was treated with complex TTM interventions in 2 studies [20,21]: In Gazang’s study [21], 220 cases of hepatitis B patients were randomly divided into integrative group and western medicine group. Interventions in the integrative group consisted of TTM and western medicine treatments. TTM treatments contained Songshi (turquoise) 25 pill in the morning, Honghua (safflower) 13 pill in the noon, and Shiliu (pomegranate) Jianwei pill at night. Interventions of western medicine were the same antiviral therapy in both groups. After a period of three to six months, results showed that effective rates were 88.1% in integrative group and 46.4% in western medicine group ($P < 0.05$).

Some Tibetan patent medicines’ effectiveness was investigated in treating different diseases. For example, Songshi 25 pill in 4 studies [22–25], and Lvronghao 25 pill [26], Gandanqing 7 granules [27], Zhangyinchen capsule [28], or Gantaishu capsule [29] in each study respectively. Xiaotong paste was investigated in treating pain such as acute stomach pain [30], soft tissue

<table>
<thead>
<tr>
<th>Outcome measure</th>
<th>Number of studies</th>
<th>Percent ($n/227$)</th>
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</thead>
<tbody>
<tr>
<td>Effectiveness</td>
<td>187</td>
<td>82.4%</td>
</tr>
<tr>
<td>Clinical symptoms</td>
<td>92</td>
<td>40.5%</td>
</tr>
<tr>
<td>Laboratory tests</td>
<td>55</td>
<td>24.2%</td>
</tr>
<tr>
<td>Clinical tests</td>
<td>27</td>
<td>11.9%</td>
</tr>
<tr>
<td>Final outcome indexes</td>
<td>15</td>
<td>6.6%</td>
</tr>
<tr>
<td>Others</td>
<td>15</td>
<td>6.6%</td>
</tr>
</tbody>
</table>

Abbreviation: RCTs, randomized controlled trials; TTM, traditional Tibetan medicine.
injuries [31], heel pain [32], low back pain [33], osteoarthritis [34], and so on.

The majority of studies (213, 93.8%) reported positive results, suggesting that the effectiveness of TTM (or TTM combined with control interventions) was superior to control interventions, and then recommending generalizing their TTM treatments to a broader clinical application. 12 studies reported neutral results, suggesting the effectiveness of TTM treatment was equivalent to that in the control group. Only 2 studies reported negative results: Zhang’s study [35] compared the effectiveness between treatment group (integration of a Tibetan drugs Sanpu Xinmao Xin capsule and fluoxetine) and control group (fluoxetine alone) in treating senile depression, showing that there was no significant difference between the two groups; Shen’s study [36] compared the effects of diclofenac diethylamine emulgel with a Tibetan external medication Qingpeng ointment on shoulder periartthritis, showing that diclofenac diethylamine emulgel was more effective in improving the function of shoulder joint than TTM treatment.

Meta-analysis could not be employed due to the inconsistency and heterogeneity of study design, participants, diseases, interventions, controls, and outcome measures.
Safety

A total of 104 (45.8%) studies reported this outcome, of which 22 studies stated that no adverse events occurred in both groups, and the remaining 83 studies reported mild adverse events. For instance, nausea occurred in patients with peptic ulcer who took antibiotic and four Tibetan medicines (Renzing changjue, Zhituo jiebai pill, Hanshuishi 21 pill, Muxiang 13 pill) at different time within one day [37]. Mild headache occurred in patients with peptic ulcer who took three Tibetan medicines (Zuozhudaxi, Mubu Yujie, Yuqiong) [38], mild stomach discomfort occurred in patient with lumbar disc herniation who took Duyiwei capsule [39], mild stomach pain occurred in female with inflammation of the reproductive system who took Guijiu 25 pill [40], and skin allergy caused by Xiaotong paste for topical analgesics [41–43]. No serious adverse effects were reported in any studies.

Methodological quality

According to pre-defined methodological quality criteria, only three studies [11,17,45] were low of bias, and the majority had high or unclear risk of bias due to the incompleteness of reporting on key methodological items. All the studies reported that participants were randomly divided into treatment group and control group, but only 7.9% (18 studies) described details on random sequence generation. Among all the studies, 4 studies [11,17,44,45] reported concealment of allocation sequence, by using sealed opaque envelope or central randomization system. 7.0% (16/227) of studies reported that blinding was used, of which 8 studies [11,13,15,17,44–47] provided sufficient information on how blinding performed and who were the objects of blinding. Dropouts during the clinical research were reported in 20 trials, of which 3 [11,17,44] used intention-to-treat analysis. Overall, the methodological quality of included trials was not promising (Fig. 5).

Discussion

Main findings of this overview

A systematic overview of RCTs on TTM which were conducted in China was presented in this paper. A total of 227 RCTs were included in this review, showing the great heterogeneous nature of the study design, sample size, diseases, treatments, outcome measurements, and methodological quality. This phenomenon was similar to Reuter KP’s review [9] on TTM clinical research available in the west, in which 40 studies including RCTs, nonrandomized controlled trials, and observational studies, involving 4684 patients were included. In his paper, all studies followed western medical diagnoses and 11 followed TTM diagnostics (syndrome differentiation), covering a wide range of diseases including respiratory, circulatory, digestive, immune, orthopedic, pediatric diseases, and hepatitis. Herbal medicines were the main treatments in TTM group; assessed outcomes included clinical outcomes such as symptom scales, laboratory tests, clinical tests, and other; heterogeneity was found in quality assessment. Meanwhile, in terms of total number of trials and study scope, TTM application and research in China seemed to be wider than those in the west.

The lists of top 10 common investigated diseases represented a tendency that TTM probably have potential advantages of treating pain, liver diseases, digestive diseases, endocrine diseases, and circulatory diseases. The integration of TTM and TCM or conventional western medicine also might be beneficial to the improvement of clinical effectiveness under some conditions. However, evidence from existing trials was weakened by methodological and reporting quality limitations. The conclusion and recommendation drew from the majority of included studies should be interpreted with caution.

Number of RCTs on TTM

According to our search, the first RCT on TTM was published in 1989 [14], later than that in the west. The number of publications increased by years especially after 2004 due to paralleled the popularization of evidence-based medicine in China [48], and probably the establishment of policy on developing and testing TTM. Publication numbers fell in 2013, possibly due to the decrement of RCTs testing single Tibetan patent medicines, and most of which were products of a single company (Tibet Cheezheng Tibetan Medicine Co., Ltd). The data in 2014 were incomplete since the search ended in June 2014 and there was a time lag of literature inclusion by databases.
The majority (99.6%, 226/227) of studies were written and published in Chinese language, only one in English language [11], and none was in Tibetan. During the hand literature search of two Tibetan medical journals (from 2007 to 2014), only one observational study was identified [49], no RCTs or other clinical studies was published in these journals. Two factors might contribute to this interesting phenomenon. One was the composition of the authors: the majority of authors of the included trials from TCM or conventional western medicine hospitals were located in interior China, were not native Tibetan speakers (the regional distribution of study sites according to provinces is presented in Fig. 3). Hence they could not write their papers in Tibetan. The other was native Tibetan-speaker authors’ preference for writing and submitting papers. From our search and screening of Tibetan journals and from discussions with native Tibetan-speaker TTM physicians, suggested that they preferred to publish their traditional theoretical study and clinical experience in Tibetan language, in order to share their opinions with TTM colleagues, and publish clinical research in Chinese language so as to make the effectiveness of TTM recognized by more readers.

Diagnosis and syndrome differentiation of diseases

A total of 103 diseases or symptoms categorized to 15 categories according to ICD-10 were investigated among the RCTs, suggesting the clinical research of TTM covered the whole medical system. The majority followed diagnosis criteria of western medicine, which could be attributed to the widely used practice of integrative medicine in China since 1950s when Chairman Mao Zedong made his famous speech on traditional Chinese medicine (TCM), saying that “TCM should integrate with western medicine organically.” Therefore, western diagnostic procedures and treatment had been integrated within the practice of traditional medicines (including TCM, TTM, and other traditional medical systems) in China since then [50].

In this review, 16.3% (37/227) of included trials were conducted in TCM hospitals, 53.7% (122/227) in western medicine hospitals, while only 22.9% (52/227) in TTM hospitals, suggesting that some TTM therapies might be available in non-TTM hospitals. After in-depth analysis, differences on syndrome differentiation among TTM and TCM/western medicine treatments were found as follows:

In trials conducted by TTM physicians, different kinds of TTM interventions were evaluated, including drug treatments for oral or external use (such as Tibetan patent medications, decoctions, medicated bath, retention enema, etc.) and non-drug treatments (including bloodletting and moxibustion). A whole medical system approach with complex TTM interventions based on TTM syndrome differentiation was applied in 19 studies, all of which were conducted by TTM physicians, accounting for 36.5% (19/52) of all studies conducted in TTM hospitals. Syndrome differentiation was not employed in the other 37 studies due to their objectives, which was to evaluate the efficacy of certain Tibetan patent medicines, other than the effectiveness of whole TTM system approach.

While for those studies conducted by TCM or conventional western medicine researchers, all the TTM interventions were just single Tibetan patent medicines, of which the majorities were obtained from single pharmaceutical companies in China (like Tibet Cheezheng Tibetan Medicine, Tibet Tibetan Medicine Group). A basic feature of TTM and TCM is the use of syndrome differentiation of diseases used to guide and determine the clinical decision. Another interesting finding of this review was that 33 studies used TCM syndrome differentiation rather than TTM to determine TTM interventions. In other words, TCM physicians used Tibetan patent medications as Chinese patent medications based on their own conventional beliefs and practices of TCM.

Methodological quality of included trials

It also important to point out that the methodological quality of included studies were generally not promising (only 7.9% of them described details of random sequence generation). As Wu T’ survey reported [51], most reports of RCTs on TCM or western medicine published in some Chinese journals lack an adequate description of randomization. This seemed to be a general phenomenon in China, as researchers (usually refers to clinicians) lacking sufficient training in clinical research methodology and reporting guidelines of clinical research papers, and many journals did not ask authors to provide methodological details. Therefore, although positive results were reported in 93.8% of the included trials in the overview, commonly the conclusions and recommendations were: “this therapy is effective and safe, we suggest its generalization in clinical practice”, any firm conclusions of recommending certain TTM treatments for corresponding diseases could not be drawn.

The designs of many studies were also problematic, especially for the applying control interventions and outcome measures. Only 6 studies used placebo controls. 76 studies used TCM treatments (53) or other TTM treatments (23) as controls, of which 71 used patent medicines approved by China’s Food and Drug Administration. However, since there was a lack of effective TTM or TCM treatments which were proved by rigorous randomized double-blind clinical trials, it was difficulty to test TTM’s effectiveness if such interventions were taken for control. Besides, in some studies, interventions in treatment group were TTM therapy combined with TCM decoctions, while the control group was conventional western medicine treatments. In this case, it was hard to differentiate the specific efficacy of TTM.

82.4% of the studies applied composite outcome index (effective rate) for effectiveness evaluation. However, the classification of “cured”, “effective”, “ineffective” within “effective rate” were not internationally accepted for its’ clinical heterogeneity among studies, and it could not reveal the specific and detailed effectiveness of TTM, either.
Limitations of this review

This review has its limitations. Firstly, despite the broad literature search, some studies in Tibetan language may not have been identified, for TTM papers could also be published in several journals of Tibetan studies (in Tibetan language) in China, as well as some informal publications for internal communication. Secondly, nearly all the included studies reported positive effects favoring TTM, with only 0.9% (2/227) having negative reports might be a reflection of publication bias in the studies covered by this review. Lastly, TTM’s RCTs conducted in China were simply consolidated by descriptive statistics, lacking of in-depth analyses. This overview could provide readers with common trends of China’s TTM clinical research, but failed to provide detailed information of TTM’s effect for a certain health condition or provide definitive data on efficacy.

Suggestions for further study

For further study, there could be two approaches. Selecting a health outcome of interest and employing a systematic review on the literature within this topic, might be more meaningful to evaluate the efficacy of TTM. Conversely, the importance on the literature within this topic, might be more meaningful a health outcome of interest and employing a systematic review methodology.

Conclusions

The results of this systematic review suggested that clinical research of TTM was propagated rapidly in China, but it is still at a nascent stage. Preliminary evidence from randomized studies have shown that TTM might have potential benefits for the management of many diseases. Studies on a definitive health outcome could be systematically reviewed so as to provide more information on TTM’s efficacy. More efforts should be made by researchers and editors to improve the quality of RCTs in China and support TTM’s further clinical application.

Authors contributions


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None.

Conflict of interest

None.

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Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at http://dx.doi.org/10.1016/j.eujim.2015.05.001.

References


